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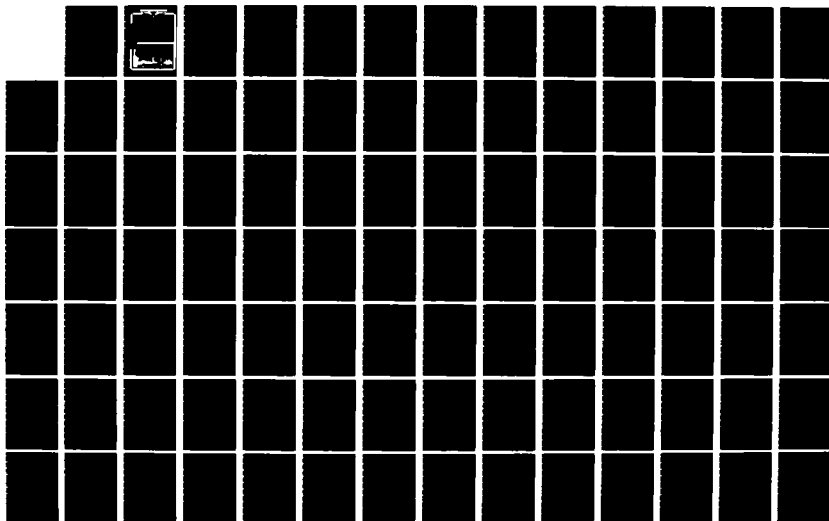
ANNUAL RESEARCH PROGRESS REPORT FOR FISCAL YEAR 1983  
(U) BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TX  
J H ANDERSON 01 OCT 83

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DEPARTMENT OF CLINICAL INVESTIGATION

# ANNUAL RESEARCH PROGRESS REPORT

FISCAL YEAR 1983

BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON, TEXAS 78234

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| REPORT DOCUMENTATION PAGE   |                                     | READ INSTRUCTIONS<br>BEFORE COMPLETING FORM                    |
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| 18. SUPPLEMENTARY NOTES<br>The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.   |                                     |  |
| 19. KEY WORDS (Continue on reverse side if necessary and identify by block number)<br>Clinical Investigations, all medical specialties<br>Investigational protocols<br>Publications, Presentations (at national, international, and regional science meetings)<br>Detail Summary Sheets to include status and key words. (cont. on reverse side)  |                                     |  |
| 20. ABSTRACT (Continue on reverse side if necessary and identify by block number)<br>Subject report identified the research activities conducted by Brooke Army Medical Center investigators through protocols approved by the Clinical Investigation Committee, the Institutional Review Board, and the Animal Care Committee and registered with the Department of Clinical Investigation during FY 1983. Report also includes known presentations and publications by the Brooke Army Medical Center staff. The research protocols described were conducted under the provisions of AR 40-38, as amended, Clinical Investigation (cont. on reverse side) |                                     |  |



Block 19. Key Words

Southwest Oncology Group  
Gynecology Oncology Group  
Polycythemia Vera Study Group  
Pediatric Oncology Group

Block 20. Abstract

Program; AR 40-7, Use of Investigational Drugs in Humans; USAMRDC 70-25; Use of Volunteers as Subjects of Research; HSC Reg 40-23, Management of Clinical Investigation Protocols and Reports; and BAMC Memo 40-98, Department of Clinical Investigation, to insure the medical well-being, preservation of rights and dignity of human subjects who participated in these investigational studies. Research studies involving the use of laboratory animals were conducted under the provisions of AR 70-18, Laboratory Animals, Procurement, Transportation, Use, Care, and Public Affairs.

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## FOREWORD

"Cheshire-Puss," she began ... "Would you tell me please, which way I ought to go from here?"

"That depends a good deal on where you want to get to," said the Cat.

"I don't much care where --" said Alice.

"Then it doesn't matter which way you go," said the Cat.<sup>1</sup>

The puzzlement for Alice is indeed one for Clinical Investigation as well. In this time of emphasis on patient care, P.T. tests, and worldwide deployability, the need for clinical investigation is questioned. This past year has been relatively good. A manpower survey gave us increased requirements, the animal facility got two 91T's and a full-time veterinarian as well as a promise of funding for renovation design, and protocols and publications were increased. In a broader view, however, clinical investigation faces some rough challenges. There have been proposals at HSC level to delete the clinical investigation authorizations. Funding has become critical with older equipment wearout increasing MEDCASE requirements tremendously. Requests for badly needed space have not been supported. Investigators have been transferred not because their skills are needed elsewhere but because of length of time in one position. One wonders if this philosophy would have sent Walter Reed to the Alaskan territories after four years in the tropics?

Clinical Investigation must communicate both its unique requirements and its value to the military medical system if it is to even survive let alone prosper. Increased emphasis on providing more services to major clinical services must be accompanied by an increased priority in resource allocation both from the MEDCEN and HSC. We must strive to continue meeting the challenges of modern medicine and the modern military.

The real credit for the work presented in this volume belongs to the clinical investigators (from principal investigators to laboratory technicians) who have devoted their time and talents to increasing medical knowledge and quality of care. Equally important are the patient volunteers who freely consented, sometimes without direct benefit to themselves, to participate in gathering new knowledge and providing a base for improved patient care.


"-- so long as I get somewhere," Alice added as an explanation.

"Oh, you're sure to do that," said the Cat, "If you only walk long enough."<sup>2</sup>

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<sup>1</sup>Carroll, L. Alice's Adventure in Wonderland, 1865.

<sup>2</sup>Ibid.

  
JAMES H. ANDERSON, JR., M.D.  
Lieutenant Colonel, MC

Chief, Department of Clinical Investigation



## UNIT SUMMARY - FISCAL YEAR 1982

### A. Objectives

The objectives of the Department of Clinical Investigation are as follows:

1. To achieve continuous improvement in the quality of patient care.
2. To assist in the professional growth and development of the house staff by providing guidance and support in clinical research.
3. To provide a milieu conducive to retention of competent staff personnel and recruitment of new personnel.
4. To provide a review body for research proposals by investigators currently assigned to MEDDAC Units in an effort to promote an interest in Army medicine and retention in the Army Medical Corps.
5. To maintain an atmosphere of inquiry consistent with the dynamic nature of the health sciences.
6. To maintain a high professional standard and accreditation of advanced health programs.
7. To assure the highest level of professional standards in the conduct of human research and animal research.

### B. Technical Approach

All research, investigational and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-7, AR 40-38, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with the applicable regulations.

### C. Staffing

| <u>Name</u>             | <u>Rank</u> | <u>MOS</u> | <u>Title</u>                   |
|-------------------------|-------------|------------|--------------------------------|
| Anderson, James H., Jr. | LTC         | 61C00      | Chief, Endocrinologist         |
| Pedersen, Carl E., Jr.  | LTC         | 68A9A      | Laboratory Director/Virologist |
| Gunn, Bruce A.*         | MAJ         | 68A00      | Microbiologist                 |
| Lieberman, Michael M.** | MAJ         | 68A00      | Microbiologist                 |
| Krikorian, Debra J.*    | CPT         | 68C00      | Biochemist                     |
| Hadick, Clayton L.*     | CPT         | 64A00      | Veterinary Lab Animal Officer  |
| Courtney, Michael G.**  | CPT         | 64A00      | Veterinary Lab Animal Officer  |
| Loyd, Charles M.        | SFC         | 92B3R      | NCOIC                          |
| Diaz, Noel              | SSG         | 92B2R      | Med Lab Specialist             |
| Sinegal, John H.**      | SSG         | 92B2R      | Med Lab Specialist             |
| Lipp, Gary***           | SP5         | 91T20      | Animal Care Specialist         |

\* Assigned 11 Jul 83; 7 Mar 83; 2 Sep 83

\*\* Reassigned 18 Jul 83; 30 Sep 83; 20 Jan 83

\*\*\*REFRAD 16 Oct 82

C. Staffing (continued)

| <u>Name</u>          | <u>Rank</u> | <u>MOS</u> | <u>Title</u>                   |
|----------------------|-------------|------------|--------------------------------|
| Bretthauer, Ricky W. | SP5         | 92B2R      | Med Lab Specialist             |
| Gregory, William T.  | SP5         | 91T20      | Animal Care Specialist         |
| Knight, Steven D.    | SP5         | 92B2       | Med Lab Specialist             |
| Tchernowitz, Clark   | SP5         | 92B2       | Med Lab Specialist             |
| Blomgren, Wendy E.   | SP4         | 91T10      | Animal Care Specialist         |
| Mead, Michael        | SP4         | 92B1R      | Med Lab Specialist             |
| Murphy, Cynthia      | SP4         | 92B1       | Med Lab Specialist             |
| Murphy, Thomas       | SP4         | 92B1       | Med Lab Specialist             |
| Davis, Geri M.       | PFC         | 92B1       | Med Lab Specialist             |
|                      | GS12        | 01310      | Research Biophysicist          |
| Merrill, Gerald A.   | GS11        | 00401      | Research Immunologist          |
| Vaughn, George K.    | GS11        | 00345      | Medical Technologist (Micro)   |
| Ayala, Eleanor       | GS9         | 00644      | Medical Technologist           |
| Peek, Michael W.     | GS9         | 01320      | Chemist                        |
| Chapa, Isidoro       | GS7         | 00645      | Medical Technician             |
| Esposito, Margaret   | GS7         | 00645      | Medical Technician             |
| Wolcott, Karen M.    | GS7         | 00404      | Biological Technician          |
| Rios, Roberto        | GS9         | 01020      | Medical Scientific Illustrator |
| Bratten, Dodie       | GS9         | 00301      | Clin Research Protocol Coord   |
| Smith, Helen J.      | GS6         | 01087      | Editorial Assistant            |

D. Funding

| <u>Type</u>                                  | <u>Fiscal Year 82</u> | <u>Fiscal Year 83</u> |
|--|-----------------------|-----------------------|
| Civilian personnel<br>to include benefits    | 136,238.00            | 212,705.00            |
| Consumable supplies                          | 199,343.00            | 175,654.00            |
| Civilian contracts<br>to include consultants | 16,381.00             | 7,883.00              |
| TDY  | 12,452.00             | 4,186.00              |
| Publications                                 | 3,511.00              | 5,129.00              |
| Noninvestment equipment<br>(Minor MEDCASE)   | 20,323.00             | 7,365.00              |
| Other OMA                                    |                       |                       |
| OMA Total                                    | 388,248.00            | 412,922.00            |
| MEDCASE                                      | 178,069.00            | 173,500.00            |
| Other  |                       |                       |
| Military                                     | 311,217.00            | 465,444.00            |
| TOTAL  | 877,534.00            | 1,051,866.00          |

## E. Progress

### Protocol Disposition FY 83

|        | <u>Terminated</u> | <u>Completed</u> | <u>Ongoing to FY 84</u> |
|--------|-------------------|------------------|-------------------------|
| FY 77  | -                 | 0                | 1                       |
| FY 78  | 1                 | 0                | 1                       |
| FY 79  | 2                 | 0                | 1                       |
| FY 80  | 2                 | 2                | 1                       |
| FY 81  | 7                 | 4                | 17                      |
| FY 82* | 8                 | 8                | 28                      |
| FY 83  | <u>5</u>          | <u>13</u>        | <u>77</u>               |
|        | 25                | 27               | 126                     |

\*C-12-82 was completed during FY 82.

### Group Protocol Disposition FY 83

|      | <u>Terminated</u> | <u>Completed</u> | <u>Ongoing to FY 84</u> |
|------|-------------------|------------------|-------------------------|
| SWOG | 1                 | 32               | 72                      |
| GOG  | 0                 | 0                | 27                      |
| PVSG | 2                 | 0                | 1                       |
| POG  | <u>0</u>          | <u>3</u>         | <u>20</u>               |
|      | 3                 | 35               | 120                     |

## F. Problems

During FY 83, principal issues concerned professional staffing and facilities. The average assigned strength for enlisted technicians was improved by direct support from the BAMC personnel staff and civilians assigned equalled authorizations. During the manpower survey, the concept of "critical mass" was again highlighted with no real resolution. This Department must be able to attract competent, proven scientists to maintain credibility within the research arena. This cannot be accomplished with only two research MSC authorizations (at the authorized grade of O-3), one MC, and one VC officer. The nucleus must be expanded to maintain a broad clinical investigation base and in addition the grade structure must be enhanced to provide incentives for career development and progression for scientists within the MEDCENs.

Renovation planning for the Laboratory Animal Facility is progressing slowly due to fiscal constraints. It is clear that the inspection by the American Association for Accreditation of Laboratory Animal Care will precede any real construction modifications and the BAMC will be in jeopardy of suspension of its accreditation. This issue is critical and needs to be resolved. The Department is also in need of adequate space for studies with infectious agents (containment laboratories) and space for human volunteer studies. These issues are being addressed internally by the Department staff with the advice of the command staff. A request for direct nursing care support has been forwarded to HSC for staffing.

Funds available for equipment procurement are satisfactory; of primary concern is the amount of time required to process paperwork through the system

(notably equipment which requires automation management approval). Funds available for the Capital Equipment Expense Program (\$1000-\$3000) are inadequate for requirements generated within this Department to support all ongoing research efforts at the BAMC; however, supply monies (<\$1000) are adequate.

# TABLE OF CONTENTS

| Project<br>Number |  | Page |
|-------------------|--|------|
|                   | Foreword   |      |
|                   | Unit Summary - Fiscal Year 1983  |      |
|                   | Publications   | 1    |
|                   | Presentations  | 11   |
|                   | Department of Clinical Investigation   |      |
| C-5-79            | Assessment of Opsonic Capacity and Phagocyte Functionality in Microliter Quantities of Whole Blood. (O) (P) (PR)   | 31   |
| C-8-79            | The Measurement of Cyclic Nucleotide Levels in Purified Populations of Lymphocytes Incubated with Mitogens. (T)  | 32   |
| C-38-79           | The Effect of Prostaglandin Synthesis Inhibitors on <u>in vitro</u> Suppressor Cell Activity in Lymphocytes from Patients with Common Variable Agammaglobulinemia. (T) | 33   |
| C-4-80            | The Development of a <u>Pseudomonas aeruginosa</u> Vaccine for Laboratory Animals, Phase II. (C) (P) (PR)  | 34   |
| C-4-81            | Chemiluminescence (CL) in Populations of Immunocompetent Cells. (O) (P) (PR)   | 35   |
| C-13-81           | Therapeutic Manipulation of Metabolic Endocrine Controls During Infection. (O)   | 36   |
| C-14-81           | Investigation of the Involvement of Endogenous Opiates in the Development of the Metabolic Pathophysiology of Infection and Endotoxin Shock. (C)                       | 37   |
| C-15-81           | Diabetogenicity of Venezuelan Equine Encephalomyelitis Virus. (T)  | 39   |
| C-28-81           | <u>In vitro</u> Synthesis of Immunoglobulins and Suppressor Cell Activity in Patients with Solid Tumors and Lymphomas on and off Therapy. (O)                          | 40   |
| C-53-81           | The Use of Monoclonal Antibody to a <u>Pseudomonas</u> Ribosomal Protein Antigen for Passive Immunization Against <u>P. aeruginosa</u> . (C) (P) (PR)                  | 41   |
| C-16-82           | The Use of Biosynthetic Human Insulin in the Treatment of Insulin-Dependent Diabetes Mellitus in Patients Who Have Never Received Insulin. (O)                         | 42   |



| Project Number |  | Page |
|----------------|--|------|
| C-43-82        | Immunogenicity of <u>Pseudomonas aeruginosa</u> ribosomal vacciner in a Cystic Fibrosis Animal Model. (T)  | 43   |
| C-64-82        | A Study of the Efficacy of a <u>Pseudomonas aeruginosa</u> Ribosomal Vaccine in the Burned Rat Model. (C)  | 44   |
| C-40-83        | Viral Infection and Diabetic Disease in Laboratory Animals. (O)  | 46   |
| C-41-83        | Rheumatoid Synovial Dendritic Cell - Its Possible Origin and Regulation of Collagenase Production. (O)   | 47   |
| C-45-83        | Development of a Chemiluminescent Enzyme Linked Immunoassay (CELIA) System for Detection of Antigens of Medical Importance in Serum and Tissue Fluids. (O) | 48   |
| C-72-83        | An Investigation into Biotyping of <u>Staphylococcus epidermidis</u> Sensu Stricto and Correlation of Biotype with Virulence and Human Disease. (O)        | 50   |
| C-73-83        | The Effect of Lysine on Herpes Simplex Virus (HSV) Infection. (O)  | 51   |

#### Department of Dentistry

##### Oral Surgery Service

|         |  |    |
|---------|--|----|
| C-62-81 | Effect of Supplemental Nasal Oxygen on the PO2 of Patients Undergoing Outpatient Oral Surgery. (O)                                   | 52 |
| C-5-81  | Evaluation of EKG Changes in Dentists Treating Awake Patients. (C)   | 53 |
| C-52-82 | A Comparison of Intravenous and Laryngotracheal Lidocaine Before Endotracheal Intubation. (C) (P)                                    | 54 |
| C-54-82 | Evaluation of PO2 Change Associated with Intravenous Sedation for Outpatient Oral Surgery. (O)                                       | 56 |
| C-59-82 | The Relationships of Soft and Hard Tissue Changes in Combined Maxillary and Mandibular Surgical Procedure. (T)                       | 57 |
| C-65-82 | Electrocardiographic Changes During Outpatient Oral Surgery. (O)   | 58 |
| C-25-83 | Determination of Transcutaneous Oxygen (PtcO2) During the Perioperative Period of Patients Undergoing Orthognathic Surgery. (O)      | 59 |
| C-59-83 | A Comparison of the Effects of Ethrane and Forane on PO2, PCO2, Blood Pressure, and Pulse When Used for Outpatient Oral Surgery. (O) | 60 |

| Project<br>Number                |  | Page |
|----------------------------------|--|------|
| C-68-83                          | Evaluation of PO <sub>2</sub> Changes During Surgical Removal of Wisdom Teeth Utilizing Enflurane Anesthesia. (O)  | 61   |
| C-76-83                          | Evaluation of Changes in Transcutaneous Oxygen and Transcutaneous Carbon Dioxide in Patients with Chronic Obstructive Pulmonary Disease While Undergoing Outpatient Oral Surgery with Intravenous Sedation and Local Anesthesia. (O) | 62   |
| Department of Emergency Medicine |  |      |
| C-32-82                          | Comparison of Speed and Complication Rate of Nasotracheal or Endotracheal Intubation by Standard Methods vs Fiber Optic Assisted Intubation. (T)   | 63   |
| C-60-82                          | The Effects of Pneumatic Trousers on Cardiovascular Hemodynamics. (O) (P)  | 64   |
| C-61-82                          | Ionizing Radiation Exposure of Emergency Room Personnel. (C)   | 65   |
| C-8-83                           | The Effect of Using Isopropyl Alcohol for Venipuncture Skin Preparation on Determining Blood Alcohol Levels. (O)   | 66   |
| C-11-83                          | The Efficacy of MAST Trousers in the Prehospital Management of Penetrating Abdominal Injuries. (O)   | 67   |
| Department of Medicine           |  |      |
| C-23-80                          | An Evaluation of Local Anesthetic Skin Testing and Progressive Challenge in Patients with a History of an Adverse Reaction to Anesthetics. (O)   | 68   |
| C-37-80                          | Assessment of Granulocyte Function and Serum Opsonic Capacity in Nephrology Patients Undergoing Dialysis. (O)  | 69   |
| C-2-81                           | Evaluation of the Coagulation, Fibrinolytic, and Humoral Immune Abnormalities Induced by Crotalus Atrox (Western Diamondback Rattlesnake) Snakebite. (O)   | 70   |
| C-3-81                           | Study of Granulocyte Function in Leukemia Patients Receiving Granulocyte Transfusions. (O)   | 71   |
| C-5-81                           | The Natural History of Patients with Large Local Reactions (LLR) Following a Hymenoptera Sting. (O)  | 72   |
| C-10-81                          | Evaluation of the Complement System and Humoral Immunity in Patients Undergoing Fibrinolytic Therapy. (T)  | 73   |
| C-12-81                          | Study of Granulocyte Function, Complement Activity and Coagulation in Patients with Adult Respiratory Distress Syndrome (ARDS). (O)  | 74   |

| Project<br>Number |   | Page |
|-------------------|---|------|
| C-29-81           | Treatment of Severe Erythema Multiforme with Systemic Steroids. (T)   | 75   |
| C-31-81           | Profile of Aortic Impedance in Patients with Congestive Cardiomyopathy. (O)   | 76   |
| C-33-81           | Renal Function in Primary Hyperparathyroidism. (O)  | 77   |
| C-34-81           | The Effect of Propranolol on Cardiac Ejection Fractions as Determined by Gated Scans in Thyrotoxic Patients. (O)  | 78   |
| C-35-81           | Hepatic Artery Embolization in the Management of Primary or Metastatic Hepatic Neoplasm. (O)  | 79   |
| C-36-81           | Comparison of Gray-Scale Ultrasonography and Computed Tomography with Infusion Nephrotomogram in Early Diagnosis of Adult-type Polycystic Kidney Disease. (C)                   | 80   |
| C-42-81           | Effects of Dietary Sodium and Potassium Intake upon the Response of the Conscious Dog to Acute Hyperkalemia: The Quantitative Role of the Liver. (T)                            | 82   |
| C-52-81           | Effect of Aspirin (ASA) on Airway Responses. (O)  | 83   |
| C-54-81           | Phosphate Homeostasis in the Normal and Renal Failure Dog. (T)  | 84   |
| C-58-81           | The Specificity of the Priming on the Nasal Mucous Membranes by Allergens and the Effect of Pharmacological Intervention. (O)   | 85   |
| C-1-82            | Chronic Cardiopulmonary Adaptations in Pentathlon Athletes. (O) (P) (PR)  | 86   |
| C-3-82            | Assessment of Sunscreen Substantivity. (O)  | 87   |
| C-8-82            | The Effect of Cimetidine on Acetaminophen (Tylenol). (T)  | 88   |
| C-10-82           | Effects of Asynchronous and Nonhomogeneous Regional Function on Global Parameters. (O) (P) (PR)   | 89   |
| C-11-81           | Open, Single-Dose Evaluation of Resting Hemodynamic Effects of Oral Nifedipine in Patients with Hypertrophic Cardiomyopathy and Acquired Left Ventricular Hypertrophy. (O) (PR) | 90   |
| C-13-82           | Intracardiac Pressure and Flow Changes Following Amyl Nitrate Inhalation. (O) (PR)  | 91   |
| C-15-82           | Percutaneous Transluminal Coronary Angioplasty, a Prospective Study on Its Indications, Use, and Efficacy. (T) (PR)   | 92   |

| Project<br>Number |  | Page |
|-------------------|--|------|
| C-24-82           | Duration of Nosocomial Oropharyngeal Colonization Following Hospitalization. (O)   | 93   |
| C-27-82           | The Role of Patient Education in Diabetes Care Utilizing Video Disc and Computer Technology. (O)   | 94   |
| C-28-82           | The Dose of Venom in Polistes Hypersensitivity. (O)  | 95   |
| C-29-82           | A Comparison of the Accuracy of Sphygmomanometric and Oscillo-metric Blood Pressure Measuring Techniques. (O)  | 96   |
| C-31-82           | Evaluation of a Non-Invasive Strategy for the Diagnosis of Coronary Artery Disease. (O)  | 97   |
| C-35-82           | Pneumococcal Meningitis. (T)   | 98   |
| C-37-82           | Evaluation of Sodium Iodate as an Adjunctive Therapy to Radioactive Iodine for Graves' Hyperthyroidism. (O)  | 99   |
| C-38-82           | Autologous Bone Marrow Transplantation in Resistant Neoplasms: A Phase I Study. (O)  | 100  |
| C-62-82           | The Effect of Calcium Channel Blockers on Sickling and Blood Viscosity in Hgb SS Disease. (O)  | 101  |
| C-63-82           | Evaluation of Catheter-Mounted Micromanometers vs External Fluid Transducers for Continuous Monitoring in the Coronary Care Unit. (O)                                    | 102  |
| C-66-82           | Detection of Immune Complexes in Serum and Synovial Fluid of Patients with Rheumatic Diseases and Other Diseases Characterized by Circulating Immune Complexes. (O) (PR) | 103  |
| C-67-82           | Pathogenesis of Tissue Injury in Porphyria. (O) (P) (PR)   | 104  |
| C-2-83            | Effect of Intravenous Administration of Didronel (Etidronate Disodium) on Serum Calcium in Patients with Hypercalcemia Due to Malignant Disease. (C)                     | 105  |
| C-3-83            | A Pilot Double-Blind Evaluation of BW942C and Placebo in Acute Nonspecific Diarrhea. (T)   | 106  |
| C-7-83            | The Clinical Effects of Four Different Topical Nitrate Preparations in Patients with Stable Angina Pectoris. (O)   | 107  |
| C-9-83            | PZA-ase Content of <u>Mycobacterium tuberculosis</u> . (C)   | 108  |
| C-10-83           | The Treatment of Cellulitis. (O)   | 109  |
| C-16-83           | Prospective Evaluation of Clinical, X-ray, Scintigraphic, and Microbiologic Characteristics of Diabetic Feet. (O)  | 110  |

| Project<br>Number |   | Page |
|-------------------|---|------|
| C-21-83           | An Investigation of Immunological Reaction to Human Serum Albumin. (O)  | 111  |
| C-22-83           | The Sputum Gram Stain and Culture in the Diagosis of Adult Community-Acquired Pneumonias. (O)   | 112  |
| C-23-83           | A Comparison of Pseudomonic Acid with Placebo in Patients with Skin Infections. (T)   | 113  |
| C-26-83           | A Study of the Transmission of the Arterial Pulse Pressures Wave Form in the Descending Aorta of Man. (O)   | 114  |
| C-27-83           | A Multi-Site Study of the Effects of Intravenous Didronel (Etidronate Disodium) on Hypercalcemia Due to Malignant Disease or Primary Hyperparathyroidism. (O)           | 115  |
| C-28-83           | Multicenter, Double-Blind, Randomized, Parallel Comparison of Two Different Dosage Regimens of Naproxen Sodium in Patients with Bone Pain Due to Metastatic Cancer. (T) | 116  |
| C-29-83           | The Effect of Intravenous Administration of Didronel (Etidronate Disodium) on Serum Calcium in Patients with Hypercalcemia Due to Malignant Disease. (O) (PR)           | 117  |
| C-33-83           | Nifedipine in Methacholine-Induced Bronchospasm. (O)  | 118a |
| C-37-83           | Short-Course Chemotherapy of Pulmonary Tuberculosis. (O)  | 118b |
| C-38-83           | Echocardiographic Evaluation of Cardiac Performance and Mitral Valve Function Under +Gz Stress. (O)   | 119  |
| C-39-83           | Mechanisms of Exercise Limitation in Patients with Obstructive Lung Disease. (O)  | 120  |
| C-42-83           | Electrolyte Abnormalities and Delirium Tremens. (O)   | 121  |
| C-51-83           | Use of Isotretinoin in Prevention of Basal Cell Carcinoma. (O)  | 122  |
| C-55-83           | Efficacy of Weekly Pulse Methotrexate in the Treatment of Rheumatoid Arthritis: A Double Bind Crossover Study. (O)  | 123  |
| C-60-83           | Nifedipine in Patients with Recurrent Episodes of Bronchospasm. (O)   | 124  |
| C-66-83           | Epidemiological, Clinical and Therapeutic Investigations into <u>Haemophilus Ducreyi</u> in American Troops in Korea. (O)   | 125  |
| C-67-83           | AdOAP-High Dose Ara-C in Adult Acute Nonlymphocytic Leukemia (ANLL). (O)  | 126  |

| Project<br>Number                       |  | Page |
|---|--|------|
| C-70-83                                 | The Study of the Safety and Efficacy of Nizatidine as an H2 Antagonist in Patients with Duodenal Ulcer Disease. (O)  | 127  |
| C-77-83                                 | High Dose Busulfan with Autologous Bone Marrow Rescue for Solid Malignancies. (O)  | 128  |
| C-78-83                                 | Dexamethasone, Diphenhydramine, Metoclopramide as Antiemetics in Cancer Chemotherapy. (O)  | 129  |
| C-79-83                                 | Investigation of Triiodothyronine Dependency Syndrome. (O)   | 130  |
| C-80-83                                 | Carbohydrate Malabsorption in the Irritable Bowel Syndrome (IBS). (O)  | 131  |
| C-83-83                                 | A Study of Genetic Susceptibility to Mountain Cedar Pollinosis. (O)  | 132  |
| C-84-83                                 | Evaluation of Systemic and Intracoronary Thrombolytic Therapy in Acute Myocardial Infarction. (O)  | 133  |
| C-95-83                                 | Effect of Micronase on Glucose Control in Poorly Controlled Type II Diabetic Subjects on Insulin Therapy. (O)  | 134  |
| Department of Nursing                   |  |      |
| C-30-82                                 | Systemic Relaxation Training Group. (T)  | 135  |
| Department of Obstetrics and Gynecology |  |      |
| C-36-82                                 | Intraoperative Intrauterine Irrigation with Cefamandole Nafate Solution at Cesarean Section versus Prophylaxis with Cefoxitin. (C)                             | 136  |
| C-55-82                                 | The Reliability of the Beta Specific Urine Pregnancy Test vs the Radioimmunoassay for Beta-HCG in Serum in the Diagnosis of Ectopic Pregnancy. (C)             | 138  |
| C-58-82                                 | The Study of Hormonin® in the Managment of Postmenopausal Symptoms. (O)  | 140  |
| C-1-83                                  | Preinduction Cervical Softening with PGE <sub>2</sub> by Administration onto the Vaginal Portion of the Cervix. (O)  | 141  |
| C-6-83                                  | Intravenous Piperacillin vs Penicillin G in Combination with Gentamicin Sulfate and Clindamycin for Postoperative Gynecological and Postpartum Infections. (O) | 142  |
| C-17-83                                 | Accelerated Clotting Time: A Rapid Evaluation of Fetal Maturity Collected from the Vaginal Pool. (T)   | 143  |

| Project Number                  |  | Page |
|---------------------------------|--|------|
| C-18-83                         | A Double Blind Comparative Study of Ritodrine versus Terbutaline on Arresting Premature Labor. (O) (P)   | 144  |
| C-30-83                         | The Derrick Protocol: The Protocol of Conservative Management of Premature Rupture of Membranes (PROM). (T)  | 145  |
| C-50-83                         | A Survey of Women Concerning Their Labor and Delivery Experiences. (O)   | 146  |
| Department of Pathology and ALS |  |      |
| C-21-80                         | <u>In vitro</u> Demyelination and Remyelination of Cultured Mammalian Central Nervous Tissue. (O)  | 147  |
| C-22-82                         | Production of Leptospira Hyperimmune Sera in Rabbits. (C)  | 148  |
| C-4-83                          | Determination of Hemophilus Species Antibiotic Sensitivities on the Vitek Gram Positive Susceptibility (GPS) Card. (C) (P) (PR)                    | 149  |
| C-5-83                          | Comparison of the API Staph Strip and AMS GPI Card for the Identification of Coagulase-Positive and Coagulase-Negative Staphylococci. (C) (P) (PR) | 150  |
| C-64-83                         | <u>In vitro</u> Demyelination and Remyelination of Cultured Mammalian Central Nervous Tissue. (O)  | 151  |
| Department of Pediatrics        |  |      |
| C-17-82                         | Beta-Thromboglobulin Levels and Platelet Function in the Newborn. (O)  | 152  |
| C-19-83                         | Comparison of Efficacy of Theophylline Administered by Continuous Infusion versus Bolus for Status Asthmaticus. (O)                                | 153  |
| C-20-83                         | Effect of Diet on Childhood Migraines. (C)   | 154  |
| C-24-83                         | Gentamicin in the Low Birth Weight Neonate. (C)  | 155  |
| C-34-83                         | Orthostatic Blood Pressure and Heart Rate Changes in Children. (C)   | 156  |
| C-69-83                         | A Study of the Inheritance Patterns of Classical 21-Hydroxylase Deficiency and Related Alleles. (O)  | 158  |
| Department of Radiology         |  |      |
| C-12-77                         | Intravenous Administration of 131-I (NP 59) for Adrenal Evaluation of Imaging. (O)   | 159  |

| Project<br>Number     |  | Page |
|-----------------------|--|------|
| C-10-83               | Hepatic Ablation with Absolute Ethanol in Dogs. (O)  | 160  |
| C-56-83               | Evaluation of Indium Oxine In-III Labeled Cellular Blood Components. (O)   | 161  |
| C-82-83               | Pediatric Urography: Open Clinical Trial with Iohexol in Patients No More than Six Years of Age. (O)               | 162  |
| Department of Surgery |  |      |
| C-21-78               | Clinical Study of Intraocular Lenses. (O)  | 163  |
| C-14-80               | Abdominal Wound Closure. (T)   | 164  |
| C-7-81                | Open-ended Cutaneous Vasostomy. (C)  | 165  |
| C-22-81               | The Effect of Prophylactic Antibiotics on Wound Sepsis Following Elective Cholecystectomy. (O)                     | 166  |
| C-30-81               | Renal Sequelae of Vasectomy. (T)   | 167  |
| C-32-81               | The Role of Continuous Peritoneal Lavage in the Treatment of Severe Acute Pancreatitis. (T)                        | 168  |
| C-41-81               | Hearing Levels in Otherwise Healthy Children Who Were Exposed to Ultrasound While Fetuses. (O)                     | 169  |
| C-57-81               | Cardiac Surgery Prospective Follow-up Project. (O)   | 170  |
| C-6-82                | Antibiotic Prophylaxis for Transurethral Resection of the Prostate (TURP). (O)                                     | 171  |
| C-14-82               | Association of Genitourinary Tract Abnormalities with Inguinal Hernia and Prognosis of Inguinal Hernia Repair. (T) | 172  |
| C-20-82               | Long-Term Effect of Orthoptics on the Fusional Vergences. (O)  | 173  |
| C-34-82               | Preoperative Detection of Gram Negative Pathogens in Intra-ocular Surgery Candidates. (O)                          | 174  |
| C-41-82               | Color Defects in Glaucoma. (O)   | 175  |
| C-12-83               | Is Routine Intraoperative Cholangiography (IOC) a Useful Adjunct to Cholecystectomy? (O)                           | 176  |
| C-13-83               | Bladder Surface Mucin - Impact on Implantation of Transitional Cell Carcinoma. (C)                                 | 177  |



| Project<br>Number |   | Page |
|-------------------|---|------|
| C-14-83           | A Comparative Study of the Effect of Two Rates of Infusion of Protamine Sulfate on the Cardiovascular System of Patients Undergoing Cardiopulmonary Bypass. (C) | 178  |
| C-32-83           | Adenocarcinoma of the Prostate - Results of Routine Urologic Screening. (C)   | 180  |
| C-35-83           | Cromolyn Sodium 4% Treatment for Vernal Conjunctivitis. (O)   | 181  |
| C-36-83           | Evaluation of the Boston Lens® and Supporting Solutions. (O)  | 182  |
| C-44-83           | The Effect of Indomethacin on Postobstructive Diuresis. (O)   | 183  |
| C-46-83           | Effect of Glucan on Immune-Mediated Inhibition of Transitional Cell Carcinoma Growth in the Murine Model. (C) (PR)  | 184  |
| C-52-83           | Effect of 1/4% Phenylephrine Nose Drops on Otitis Media and Serous Otitis. (O)  | 185  |
| C-53-83           | Occupational History and Low Back Pain. (O)   | 186  |
| C-54-83           | Plastafil Carbon-Fiber Implant Study. (O)   | 187  |
| C-56-83           | A Clinical Study Comparing the Efficacy of Fenoprofen Calcium, Phenylbutazone, and Placebo in the Treatment of Acute Soft Tissue Injuries. (O)                  | 188  |
| C-57-83           | Circulatory Responses to Laryngoscopy with Miller or MacIntosh Blades. (C)  | 189  |
| C-61-83           | Impact of the Unilateral Ureteral Obstruction on Renal Excretion of Calcium and Phosphate. (O)  | 190  |
| C-62-83           | Intravitreal Injection of Beta-Lactam Antibiotics. (O)  | 191  |
| C-63-83           | Dose-Response Relationship of Cyclophosphamide in Murine Transitional Cell Carcinoma. (O)   | 192  |
| C-71-83           | Measurement of Myocardial Oxygen Consumption in Various Modes of Partial Left Heart Bypass. (O)   | 193  |
| C-74-83           | Coagulum Pyelolithotomy Using Cryoprecipitate with or without the Use of Thrombin. (O)  | 194  |
| C-75-83           | The Preservation of Cellular Architecture by Verapamil During Renal Artery Occlusion. (O)   | 195  |

| Project<br>Number |   | Page |
|-------------------|---|------|
| C-81-83           | Chronic Administration of Nifedipine and the Cardiovascular Responses to High-Dose Fentanyl Anesthesia and Coronary Artery Bypass Grafting in Man. (O)              | 196  |
|                   | Medical Physics Service   |      |
| C-31-82           | Evaluation of Radiation Exposure to Personnel During Cardiac Catheterization. (O)   | 197  |
|                   | Nutrition Care Division   |      |
| C-21-82           | A Predictive Model for Estimating the Response to the Army Physical Fitness and Weight Control Program. (O)   | 198  |
|                   | Physical Medicine and Rehabilitation Service  |      |
| C-31-83           | A Comparison of Handling Errors During Facilitation of Head Control in High Risk Infants by Parents Exposed to Different Strategies for Learning a Motor Skill. (C) | 199  |
|                   | Academy of Health Science   |      |
|                   | <u>Physical Therapy Section</u>   |      |
| C-85-83           | A Comparison of the Hold-relax and Fluori-methane Spray Procedures in Increasing Hamstring Flexibility. (O)   | 200  |
| C-86-83           | Comparison of Submaximal versus Maximal Warm-ups on Isokinetic Tests. (O)   | 201  |
| C-87-83           | The Effects of Gravity Guided Lumbar Traction on Intravertebral Dimensions in the Lumbar Spine. (O)   | 202  |
| C-88-83           | Analysis of a Method of Measuring Pelvic Tilt. (O)  | 203  |
| C-89-83           | A Comparative Analysis of the U.S. Army's Method for Determining Body Fat Content. (O)  | 204  |
| C-90-83           | Comparison of Using Heat versus Heat and Cold During Stretching to Improve Flexibility. (O)   | 205  |
| C-91-93           | The Effect of Arthroscopic Debridement and Washout on the Degenerative Knee as Demonstrated on the Cybex II Isokinetic Dynamometer. (O)                             | 206  |
| C-92-83           | The Influence of Warm Water Immersion on Muscle Tension as Measured by Electromyography in Hemiplegic Patients. (O)   | 207  |
| C-93-83           | Eye Movement and Its Effect on Suboccipital Muscle Activity. (O)  | 208  |

| Project Number |  | Page |
|----------------|--|------|
| C-94-83        | Quadriceps Strength in Open Versus Closed Minisectomy. (O)   | 209  |
|                | Darnall Army Hospital  |      |
| C-1-78         | Tetracycline-induced Ultraviolet Fluorescence of Pathologic Pulmonary Tissues as Viewed Through the Fiberoptic Bronchoscope. (T)   | 210  |
| C-43-83        | Comparison of Changes in Blood Pressure and Heart Rate with Metocurine and d-Tubocurarine. (O)   | 211  |
| C-47-83        | A Comparison of the Incidence of Transient Bacteremias Following Prophylaxis with a Rubber Cup and Prophylactic Paste Compared to that Following Prophylaxis with the Propy Jet®. (C)  | 212  |
| C-48-83        | An Evaluation of the Efficacy of Electroacupuncture in the Treatment of Temporomandibular Joint Pain. (O)  | 213  |
| C-49-83        | The Effect of the Periodontal Ligament on Obtaining Adequate Local Anesthesia for Extraction of Erupted Mandibular Molars and Bicuspids. (O)   | 214  |
| C-65-83        | Perinatal Hyperviscosity. (O)  | 215  |
|                | Reynolds Army Hospital   |      |
| C-39-82        | Comparison of Electrosurgery and Surgical Blade Loops in the Removal of Inflammatory Papillary Hyperplasia. (C)  | 216  |
|                | Southwest Oncology Group   |      |
| SWOG 7713      | Chemoimmunotherapy in Non-Hodgkin's Lymphoma. (C)  | 217  |
| SWOG 7727      | Combination Chemoimmunotherapy Utilizing, BCNU, Hydroxyurea and DTIC with Levamisole vs DTIC plus Actinomycin-D in the Treatment of Patients with Disseminated Malignant Melanoma. (C) | 218  |
| SWOG 7804      | Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma. (O)                            | 219  |
| SWOG 7808      | Combination Modality Treatment for Stage III and IV Hodgkin's Disease MOPP 6.  | 220  |
| SWOG 7823      | ROAP-AdOAP in Acute Leukemia. (O)  | 221  |
| SWOG 7827      | Combined Modality Therapy for Breast Carcinoma, Phase III. (O)   | 222  |

| Project<br>Number |  | Page |
|-------------------|--|------|
| SWOG 7841         | Phase II-III Comparison of FAM vs FAM + Vincristine vs Chlorozotocin in the Treatment of Advanced Gastric Adenocarcinoma. (O)  | 223  |
| SWOG 7902         | Combined Modality Therapy for Head and Neck Cancer. (C)  | 224  |
| SWOG 7916         | Phase II Evaluation of Gallium Nitrate in Metastatic Urological Malignancies: Testicular, Bladder, Prostate and Kidney. (O)  | 225  |
| SWOG 7922         | Combination of CTX, Adria and Cis-Platinum vs m-AMSA in Patients with Advanced Transitional Cell Cancer of the Urinary Bladder with Good Renal Function, Phase II-III. (C)                       | 226  |
| SWOG 7924         | Multimodal Therapy for Limited Small Cell Carcinoma of the Lung, Phase III. (C)  | 227  |
| SWOG 7925         | Chemoimmunotherapy in Stages III and IV Ovarian Carcinoma: A-C plus BCG, vs A-C plus Cis-Platinum, vs A-C plus Cis-Platinum plus BCG, Phase III. (O)   | 228  |
| SWOG 7927         | Chemotherapy for Multiple Myeloma, Phase III. (C)  | 229  |
| SWOG 7936         | Evaluation of Mitomycin-C + Vincristine + Bleomycin + Cis-Platinum vs Mitomycin-C + Cis-Platinum vs Cis-Platinum in the Treatment of Disseminated Carcinoma of the Uterine Cervix, Phase II. (C) | 230  |
| SWOG 7937         | Evaluation of m-AMSA in Metastatic Carcinoma of the Genito-urinary Tract Except Renal Carcinoma, Phase II. (C)   | 231  |
| SWOG 7956         | Study of Postinfarction Nephrectomy and Medroxyprogesterone Acetate (Depo-Provera) in Metastatic Renal Cell Carcinoma. (O)   | 232  |
| SWOG 7958         | Evaluation of m-AMSA in Metastatic or Recurrent Epithelial Carcinomas of the Female Genital Tract. (C)   | 233  |
| SWOG 7983         | Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain, Phase I and II. (O)  | 234  |
| SWOG 7984         | Treatment of Chronic Stage CML with Pulse, Intermittent Busulfan Therapy with or without Oral Vitamin-A, Phase III. (O)  | 235  |
| SWOG 7990         | Testicular Cancer Intergroup Study: (O)  | 236  |
| SWOG 8001         | Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III. (O)  | 237  |

| Project<br>Number |  | Page |
|-------------------|--|------|
| SWOG 8005         | Evaluation of DHAD in Refractory Malignant Lymphomas, Phase II - Pilot. (C)  | 238  |
| SWOG 8006         | Postoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx, or Larynx, Phase III. (O)  | 239  |
| SWOG 8008         | Evaluation of Dihydroxyanthracenedione (DHAD) in Refractory Breast Cancer, Phase II. (C)   | 240  |
| SWOG 8009         | Evaluation of DHAD in Patients with Refractory Small Cell Lung Cancer, Phase II. (C)   | 241  |
| SWOG 8012         | Treatment for Advanced Adenocarcinoma and Large Cell Carcinoma of the Lung: FOMi vs CAP vs FOMi/CAP, Phase III. (C)  | 242  |
| SWOG 8015         | Evaluation of Two Combination Chemotherapy Programs, Adriamycin and Cis-Platinum (AP) vs Adriamycin, Cis-platinum plus VP-16 (VAP) in the Treatment of Extensive Squamous Cell Carcinoma of the Lung, Phase III. (C) | 243  |
| SWOG 8017         | 5-FU, Adriamycin, Streptozotocin and Cyclophosphamide (FAC-S) in the Treatment of Metastatic Carcinoid Tumors, Phase II. (O)   | 244  |
| SWOG 8020         | Adriamycin + VP-16 vs Adriamycin Alone in Advanced Adenocarcinoma of the Breast, Phase II. (C)   | 245  |
| SWOG 8024         | Combined Modality Therapy for Disseminated Soft Tissue Sarcomas, Phase III. (O)  | 246  |
| SWOG 8025         | Combination Chemotherapy for Chronic Lymphocytic Leukemia. (O)   | 247  |
| SWOG 8026         | Cis-Platinum in the Treatment of Refractory Epidermoid Carcinoma of the Penis, Phase II. (C)   | 248  |
| SWOG 8027         | The Natural History of Pathological Stage T <sub>1-2</sub> N <sub>0</sub> M <sub>0</sub> ER+ Breast Cancer, Phase III. (C)   | 249  |
| SWOG 8030         | Evaluation of DHAD in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase II. (O)   | 250  |
| SWOG 8031         | Evaluation of DHAD in Refractory Multiple Myeloma, Phase II. (C)   | 251  |
| SWOG 8032         | Evaluation of DHAD in Acute Leukemia, Phase II. (C)  | 252  |
| SWOG 8037         | Combined Therapies for Squamous Cell Carcinoma of the Esophagus, Phase II. (O)   | 253  |

| Project<br>Number |   | Page |
|-------------------|---|------|
| SWOG 8038         | Vinblastine in Advanced Ovarian Cancer, Phase II. (O)   | 254  |
| SWOG 8040         | Evaluation of Combination Chemotherapy (FAM-S) vs a Phase II Drug in Pancreatic Adenocarcinoma, Phase II. (O)   | 255  |
| SWOG 8042         | Evaluation of MGBG in Pancreatic Adenocarcinoma, Phase II. (O)  | 256  |
| SWOG 8044         | Evaluation of AZQ in Pancreatic Carcinoma, Phase II. (O)  | 257  |
| SWOG 8049         | The Treatment of Resected, Poor Risk Prognosis Malignant Melanoma: Stage I: Surgical Excision vs Surgical Excision + Vitamin A, Phase III. (O)                                | 258  |
| SWOG 8051         | Evaluation of L-Alanosine in Acute Leukemia, Phase II. (C)  | 259  |
| SWOG 8066         | Adjuvant Intrahepatic Chemotherapy with Mitomycin-C and 5-FU Combined with Hepatic Radiation in High Risk Patients with Carcinoma of the Colon, Phase II - Pilot. (C)         | 260  |
| SWOG 8077         | Combined Chemotherapy and Hormonal Therapy for Recurrent or Disseminated ER+ Breast Cancer, PACT vs ACT, Phase II. (C)  | 261  |
| SWOG 8092         | Use of Human Tumor Cloning System to Select Chemotherapy for Patients with Ovarian Cancer Refractory to Primary Therapy, Ancillary Study. (O)                                 | 262  |
| SWOG 8093         | Treatment of Metastatic Malignant Mesothelioma: A Comparison of Cyclophosphamide (Cytosan), DTIC and Adriamycin (CIA) vs Cyclophosphamide and Adriamycin (CA), Phase III. (O) | 263  |
| SWOG 8094         | Radiotherapy with and without Chemotherapy for Malignant Mesothelioma Localized to One Hemithorax, Phase III. (O)   | 264  |
| SWOG 8101         | VM-26 in Advanced GU Cancer, Phase II. (C)  | 265  |
| SWOG 8102         | Whole Brain Irradiation and Intrathecal Methotrexate in the Treatment of Solid Tumors Leptomeningeal Metastases. Phase II. (O)  | 266  |
| SWOG 8104         | Treatment of Advanced Seminoma (Stage cII (N <sub>4</sub> ) + cIII) with Combined Chemotherapy and Radiation Therapy, Phase II. (O)   | 267  |
| SWOG 8106         | Evaluation of AZQ (Carbamic Acid) in Central Nervous System Tumors, Phase II. (O)   | 268  |
| SWOG 8107         | Management of Disseminated Melanoma, Master Protocol, Phase II-III. (O)   | 269  |

| Project<br>Number |  | Page |
|-------------------|--|------|
| SWOG 8108         | Evaluation of Bisantrene Hydrochloride in Refractory Multiple Myeloma, Phase II. (O)   | 270  |
| SWOG 8110         | Treatment of Advanced Germ Cell Neoplasms of the Testis: A Comparison of Remission Induction...vs Observation, Phase III. (O)  | 271  |
| SWOG 8111         | The Treatment of Resected, Poor Prognosis Malignant Melanoma: Stage II - Surgical Excision vs Surgical Excision + Vitamin A vs Surgical Excision + Actinomycin D and DTIC. (O)                                     | 272  |
| SWOG 8112         | Combination Chemotherapy of Unfavorable Histology Non-Hodgkin's Lymphoma with CHOP and CVB, Phase II. (C)  | 273  |
| SWOG 8116         | Evaluation of Bisantrene Hydrochloride in Refractory Lymphoma, Phase II. (O)   | 274  |
| SWOG 8117         | Evaluation of Bisantrene Hydrochloride in Refractory Ovarian Cancer, Phase II. (C)   | 275  |
| SWOG 8118         | Evaluation of Bisantrene Hydrochloride in Refractory Malignant Melanoma, Phase II. (O)   | 276  |
| SWOG 8119         | Evaluation of Bisantrene Hydrochloride in Hepatoma. (O)  | 277  |
| SWOG 8120         | Evaluation of Bisantrene Hydrochloride in Gastric Carcinoma, Phase II. (O)   | 278  |
| SWOG 8122         | Combined Modality Treatment of Extensive Small Cell Lung Cancer, Phase III. (O)  | 279  |
| SWOG 8124         | Treatment of Acute Non-Lymphocytic Leukemia with Conventional Induction, Consolidation Chemotherapy: Maintenance with Chemotherapy vs Bone Marrow Transplantation Following Total Body Irradiation, Phase III. (O) | 280  |
| SWOG 8161         | Evaluation of Bisantrene Hydrochloride in Adult Acute Leukemia, Phase II - Pilot. (O)  | 281  |
| SWOG 8200         | Evaluation of Vinblastine by Continuous Infusion for Advanced Recurrent Endometrial Carcinoma, Phase II. (O)   | 282  |
| SWOG 8203         | Randomized Comparison of Adriamycin, Mitoxantrone and Bisantrine in Patients with Metastatic Breast Cancer not Previously Exposed to Intercalating Chemotherapy, Phase III. (O)                                    | 283  |
| SWOG 8206         | Evaluation of Aclacinomycin-A in Colorectal Carcinoma, Phase II. (C)   | 284  |
| SWOG 8207         | AZQ in Advanced Renal Cell Carcinoma, Phase II. (O)  | 285  |

| Project<br>Number |   | Page |
|-------------------|---|------|
| SWOG 8208         | Trial of Chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma Phase II. (O)  | 286  |
| SWOG 8209         | A Study of AZQ in Soft Tissue and Bony Sarcomas, Phase II. (O)  | 287  |
| SWOG 8210         | A Comparison of Aggressive Radiotherapy + Chemotherapy vs Aggressive Chemotherapy in the Treatment of Limited Carcinoma of the Pancreas, Phase III. (O)   | 288  |
| SWOG 8211         | Evaluation of Cis-Diamminedichloroplatinum in Disseminated Gastric Adenocarcinoma, Phase II. (O)  | 289  |
| SWOG 8213         | Evaluation of Aclacinomycin-A in Refractory Multiple Myeloma, Phase II. (C)   | 290  |
| SWOG 8214         | Evaluation of Bisantene Hydrochloride in Advanced Sarcoma, Phase II. (O)  | 291  |
| SWOG 8215         | Comparison of Combination Chemotherapy with VP-16 and Cis-Platinum vs BCNU, Thiotepa, Vincristine and Cyclophosphamide in Patients with Small Cell Carcinoma of the Lung Who Have Failed or Relapsed Primary Chemotherapy, Phase III. (O) | 292  |
| SWOG 8217         | Evaluation of Spirogermanium in Adenocarcinoma of the Prostate, Phase II. (O)   | 293  |
| SWOG 8218         | Evaluation of Spirogermanium in Renal Cell Carcinoma. (C)   | 294  |
| SWOG 8219         | Evaluation of Combined or Sequential Chemo-Endocrine Therapy in Treatment of Advanced Adenocarcinoma of the Prostate, Phase III. (O)  | 295  |
| SWOG 8223         | Master Protocol: Randomized Comparison of Drug Therapy for Squamous Cell Cancer of the Head and Neck with Early Assessment Phase II Agents, Phase III. (O)  | 296  |
| SWOG 8228         | Correlation Between Progesterone Receptor and Response to Tamoxifen in Patients with Newly Diagnosed Metastatic Breast Disease, Phase II. (O)   | 297  |
| SWOG 8229         | Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy + Vincristine-Prednisone for Maintenance or Consolidation. Phase II. (O)                | 298  |
| SWOG 8231         | Chemotherapy for Extragonadal Germinal Cell Neoplasms, Phase II. (O)  | 299  |



| Project<br>Number |  | Page |
|-------------------|--|------|
| SWOG 8232         | Treatment of Limited Small Cell Lung Cancer with VP-16/Cis-Platinum, Alternating with Vincristine/Adriamycin/Cyclophosphamide and Radiation Therapy vs Concurrent VP-16/Vincristine/Adriamycin...Radiation Therapy, Phase III. (O) | 300  |
| SWOG 8237         | Evaluation of Continuous Infusion Vinblastine Sulfate in Pancreatic Adenocarcinoma, Phase II. (O)  | 301  |
| SWOG 8239         | Evaluation of Spirogermanium in CNS Tumors, Phase II. (O)  | 302  |
| SWOG 8241         | Treatment of Advanced Non-Small Cell Lung Cancer: PVpvs PVpM vs PVe vs PVeMi vs FOMi/CAP, Phase III. (O)   | 303  |
| SWOG 8244         | Clinical Antitumor Activity of Vinblastine Sulfate in Diffuse Mesothelioma, Phase II. (O)  | 304  |
| SWOG 8245         | Combination Chemotherapy of Unfavorable Histology Non-Hodgkin's Lymphoma with CHOP and CVB (Alternating), Phase II. (O)  | 305  |
| SWOG 8263         | Combined Radiation Therapy and Chemotherapy as Adjuvant Treatment for Duke's B2-C Colon Cancer, Phase I-II, Pilot. (O)   | 306  |
| SWOG 8264         | Combination Chemotherapy with m-AMSA, Cis-Platinum and MGBG for Refractory Lymphoma, Phase II. (O)   | 307  |
| SWOG 8269         | Concurrent Chemo-Radiotherapy for Limited Small Cell Carcinoma of the Lung, Phase II - Pilot. (O)  | 308  |
| SWOG 8291         | The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study #1. A Randomized Trial of Adjuvant Doxorubicin versus Standard Therapy (A Delay of Chemotherapy Until the Time of Possible Relapse). (O)                                   | 309  |
| SWOG 8292         | Treatment for Brain Metastases, Phase III. Intergroup Study. (O)   | 310  |
| SWOG 8294         | Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer, (ECOG EST-1180), Intergroup, Study (Observation Only) (Patients Randomized to CMFP Chemotherapy). (O)                     | 311  |
| SWOG 8303         | Evaluation of 2'Doxycorubicin in Refractory Multiple Myeloma, Phase II. (O)  | 312  |
| SWOG 8304         | Evaluation of L-Alanosine in Metastatic Carcinoma of the Breast. (O)   | 313  |
| SWOG 8305         | Chemotherapy of Metastatic Colorectal Carcinoma with 5-FU and Folinic Acid, Phase II.  | 314  |

| Project Number            |  | Page |
|---------------------------|--|------|
| SWOG 8311                 | Combination Chemotherapy with Cis-Platinum, Vinblastine, and Methylglyoxal Bis (Guanylhydrazone) (MGBG) in Epidermoid Carcinoma of the Esophagus. (O)  | 315  |
| SWOG 8360                 | Use of the Surgically Implanted "Infusaid" Pump for Ambulatory Outpatient Hepatic Arterial Chemotherapy for Patients with Colon Cancer Metastatic to the Liver, Phase II - Pilot. (O)              | 316  |
| SWOG 8391                 | The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study Protocol #2: A Randomized Trial of Adjuvant Doxorubicin (Adriamycin) vs Standard Therapy. (O)  | 317  |
|                           | Aclacinomycin - Phase II Evaluation in Lung Cancer - Pilot Study. (T)  | 318  |
| Gynecology Oncology Group |  |      |
| GOG 20                    | A Randomized Comparison of Adriamycin vs No Further Therapy in Patients with Uterine Sarcomas, Stage I and II, Phase III. (O)  | 319  |
| GOG 24                    | Treatment of Women with Cervical Cancer Stage IIB, IIIB, IVA, Confined to the Pelvis and/or Para-Aortic Nodes with Radiotherapy Alone vs Radiotherapy plus Immunotherapy, Phase II. (O)            | 320  |
| GOG 25                    | A Randomized Comparison of Melphalan Therapy Alone vs Melphalan plus Immunotherapy (C. Parvum) in the Treatment of Women with Stage III (Optimal) Epithelial Carcinoma of the Ovary, Phase II. (O) | 321  |
| GOG 26                    | Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies. (O)   | 322  |
| GOG 34                    | A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma, Stage I, and Occult Stage II. (O)                            | 323  |
| GOG 36                    | Surgical-Pathologic Study of Women with Squamous Cell Carcinoma of the Vulva. (O)  | 324  |
| GOG 37                    | Randomized Study of Radiation Therapy vs Pelvic Node Resection for Patients with Invasive Squamous Cell Carcinoma of the Vulva Having Positive Groin Nodes. (O)                                    | 325  |
| GOG 40                    | A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas. (O)  | 326  |

| Project<br>Number |  | Page |
|-------------------|--|------|
| GOG 41            | Surgical Staging of Ovarian Carcinoma. (O)   | 327  |
| GOG 42            | Treatment of Recurrent or Advanced Uterine Sarcoma. A Randomized Comparison of Adriamycin vs Adriamycin and Cyclophosphamide, Phase III. (O)   | 328  |
| GOG 43            | A Randomized Comparison of Cis-Platinum 50 mg/m <sup>2</sup> Every 3 Weeks vs Cis-platinum 100mg/m <sup>2</sup> IV Every 3 Weeks vs Cis-platinum 20 mg/m <sup>2</sup> IV Daily x 5 Days in Treatment of Patients with Advanced Carcinoma of the Cervix, Phase III. (O) | 329  |
| GOG 44            | Evaluation of Adjuvant Vincristine, Dactinomycin, and Cyclophosphamide Therapy in Malignant Germ Cell Tumors of the Ovary After Resection of all Gross Tumor, Phase III. (O)   | 330  |
| GOG 45            | Evaluation of Vinblastine, Bleomycin, and Cis-platinum in Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary, Phase III. (O)   | 331  |
| GOG 46            | A Randomized Comparison of Melphalan vs Intraperitoneal Chromic Phosphate in the Treatment of Women with Stage I (exclusive of Stage IA(i) G1 and IB(i) G1) Epithelial Carcinoma of the Ovary, Phase II. (O)   | 332  |
| GOG 47            | A Randomized Study of Adriamycin + Cyclophosphamide vs Adriamycin + Cyclophosphamide + Cis-platinum in Patients with Advanced Ovarian Adenocarcinoma - Suboptimal Stage II, Stage IV and Recurrent, Phase III. (O)   | 333  |
| GOG 48            | A Study of Progestin Therapy and a Randomized Comparison of Adriamycin vs Adriamycin + Cyclophosphamide in Patients with Endometrial Carcinoma After Hormonal Failure, Phase III. (O)  | 334  |
| GOG 49            | A Surgical-Pathologic Study of Women with Invasive Carcinoma of the Cervix Stage IB and Randomly Assigned Radiation Therapy versus No Further Therapy in Selected Patients. (O)  | 335  |
| GOG 50            | A Study of Adriamycin as Postoperative Therapy for Ovarian Sarcoma, Primary or Recurrent, with No Prior Chemotherapy, Phase III. (O)   | 336  |
| GOG 51            | A Randomized Comparison of Droperidol versus THC in the Treatment of Nausea and Vomiting Produced by Cis-platinum Chemotherapy for Gynecologic Malignancies. (O)   | 337  |
| GOG 52            | A Phase III Randomized Study of Cyclophosphamide plus Adriamycin plus Platinol (Cis-platinum) vs Cyclophosphamide plus Platinol in Patients with Optimal Stage III Ovarian Adenocarcinoma. (O)   | 338  |

| Project Number                |   | Page |
|-------------------------------|---|------|
| GOG 56                        | A Randomized Comparison of Hydroxyurea vs Misonidazole as an Adjunct to Radiation Therapy in Patients with Stages IIB, III and IVA Carcinoma of the Cervix and Negative Para-Aortic Nodes. (O)  | 339  |
| GOG 59                        | A Randomized Comparison of Extended Field Radiation Therapy and Hydroxyurea Followed by Cisplatin or No Further Therapy in Patients with Cervical Squamous Cell Carcinoma Metastatic to High Common Iliac...Lymph Nodes, Phase III. (O) | 340  |
| GOG 60                        | A Randomized Study of Doxorubicin plus Cyclophosphamide plus Cisplatin vs Doxorubicin plus Cyclophosphamide plus Cisplatin plus BCG in Patients with Advanced Suboptimal Ovarian Adenocarcinoma, Stage III and IV. (O)                  | 341  |
| GOG 61                        | Randomized Study of Cis-Platinum + Cyclophosphamide vs Hexamethylmelamin after Second-Look Surgery in Nonmeasurable Stage III Ovarian Adenocarcinoma Partially Responsive to... Cis-Platinum and Cyclophosphamide. (O)                  | 342  |
| 7601                          | Ovarian Cancer Study Group Protocol for Selected Stage IAi - IBi Ovarian Cancer (Well and Moderately Differentiated). (O)   | 343  |
| 7602                          | Ovarian Cancer Study Group Protocol for All Stage IC and II (A,B,C) and Selected Stage IAii and IBii Ovarian Cancer. (O)  | 344  |
| Polycythemia Vera Study Group |   |      |
| PVSG-12                       | Hydroxyurea in Thrombosis. (O)  | 345  |
| PVSG-13                       | Study of the Clinical Features and Natural History of Asymptomatic Patients with Myeloproliferative Disorders. (T)  | 346  |
| PVSG-15                       | Efficacy Trial Using Cyproheptadine and Cimetidine for Pruritus in Polycythemia Vera: (T)   | 347  |
| Pediatric Oncology Group      |   |      |
| POG 7376                      | Evaluation of Natural History of Histiocytosis X in Childhood. (O)  | 348  |
| POG 7612                      | MOPP + Bleo vs A-COPP with IF RT in Stage III Hodgkin's Disease in Children. (O)  | 349  |
| POG 7621                      | MOPP vs OPP in the Treatment of Children with Recurrent Brain Tumors. (O)   | 350  |
| POG 7712                      | Comparison of Treatment Regimens for the First CNS Relapse in Children with Acute Lymphocytic Leukemia - CNS #6. (O)  | 351  |

| Project<br>Number |  | Page          |
|-------------------|--|---------------|
| POG 7799          | Rare Tumor Registry for Childhood Solid Tumor Malignancies.<br>(O)   | 352           |
| POG 7812          | Anguidine in Central Nervous System Tumors. (C)  | 353           |
| POG 7818          | Rubidazone in Children with ALL and AML in Relapse. (C)  | 354           |
| POG 7829          | Comparison of Two Dose Regimens of Intrathecal Methotrexate<br>for CNS Leukemia, Phase II. (O)   | 355           |
| POG 7834          | Second Induction Maintenance in Acute Lymphocytic Leukemia,<br>Phase III. (O)  | 356           |
| POG 7837          | Evaluation of Systemic Therapy for Children with T Cell Acute<br>Lymphatic Leukemia, Phase III. (O)  | 357           |
| POG 7843          | Evaluation of Rubidazone in the Treatment of Children with<br>Solid Tumors, Phase II. (O)  | 358           |
| POG 7895          | Multimodal Therapy for Management of Primary Non-Metastatic<br>Ewing's Sarcoma of Pelvic and Sacral Bones. (O)                                     | 359           |
| POG 7901          | Rescue Therapy for Non-CNS Extramedullary Disease in Children<br>with Acute Lymphoblastic Leukemia, Phase III. (O)                                 | 360           |
| POG 7909          | Evaluation of MOPP Adjuvant Chemotherapy in the Treatment of<br>Localized Medulloblastoma and Ependymoma. (O)                                      | 361           |
| POG 7919          | Evaluation of m-AMSA in Children with Acute Leukemia and<br>Non-Hodgkins in Relapse. (C)   | 362           |
| POG 8000          | National Wilms' Tumor Study, III. (O)  | 363           |
| POG 8002          | Combination Chemotherapy with Adriamycin, Cis-Platinum,<br>Vincristine, and Cytosan in Children with Metastatic Neuro-<br>blastoma (Stage IV). (O) | 364           |
| POG 8035          | Laboratory Subclassification and Evaluation of Treatment<br>Regimens in Acute Lymphoid Leukemia in Childhood. (O)                                  | 365           |
| POG 8075          | Circulating Immune Complexes in Pediatric Malignancies. (O)  | 366           |
| POG 8104          | Comprehensive Care of the Child with Neuroblastoma: A Stage<br>Age Oriented Study, Phase III. (O)  | 367           |
|                   | Author Index   | 368           |
| Code:             | C - Completed  | P - Published |
|                   | O - Ongoing  | PR - Present  |
|                   | T - Terminated   |               |

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Thompson, I.M., Wesen, C.A. Prostatism and inguinal hernia. 1984 Year Book of Surgery (in press).

#### PHARMACY SERVICE

Sikora, R.G. Planning and implementing a mobile decentralized unit dose system. Milit Med 148:141-144, Feb 83.

Dasher, T. Hyperalimentation order calculations using a computer.  
Hospital Pharmacy, 18(5):239-249, May 83.

PHYSICAL MEDICINE AND REHABILITATION SERVICE

Riggan, J.S. Learning disabled adult becomes productive soldier: case report. Milit Med, Nov 82.

Riggan, J.S. A learning abilities program for learning disabled soldiers. Occupational Therapy in Mental Health, Vol 3:2, 1983.

Ellsworth, P.D. Army psychiatric occupational therapy: from the past and into the future. Occupational Therapy in Mental Health, Vol 3:2, 1983.

DEPARTMENT OF THE ARMY  
Brooke Army Medical Center  
Fort Sam Houston, Texas 78234  
DEPARTMENT OF CLINICAL INVESTIGATION

PRESENTATIONS

OFFICE OF THE COMMANDER

Strevey, T.E., Jr. Management of cardiothoracic battlefield casualties.  
American College of Surgeons, 10-14 Apr 83, Washington, DC.

DEPARTMENT OF CLINICAL INVESTIGATION

Allen, R.C. Quantification and differentiation of polymorphonuclear leukocyte oxygenation activities by chemiluminogenic probing. Third International Conference on Oxygen Radicals in Chemistry and Biology, 10-15 Jul 83, Neuherberg/Munchen, Germany. (C)

Allen, R.C. Fundamental aspects and applications of phagocyte associated luminescence. 15th FEBS, 24-29 Jul 83, Brussels, Belgium. (C)

Allen, R.C. Participant in immunotechnology symposium, 15th FEBS, 24-29 Jul 83, Brussels Belgium. (C)

Anderson, J.H., Jr. Faculty member "The Ethical, Legal, and Regulatory Dilemmas in Research with Human Subjects." University of Texas Health Science Center and FDA, 18-20 Apr 83, Dallas, Texas.

Anderson, J.H., Jr. Invited lecturer. University of Texas Health Science Center at San Antonio, Department of Medicine, Endocrinology Service, Oct 82, Feb 83, and May 83.

Anderson, J.H., Jr. Diabetic ketoacidosis and nonketotic hyperosmolar coma. Southern Medical Association, 20 Aug 83, San Antonio, TX. (C)

Burleson, D.G. Comparison of guinea pig peritoneal macrophage and granulocyte oxygenation activities in response to lectins. FASEB, 10-15 Apr 83, Chicago, IL. (C)

Gregory, W. Immunotherapy and chemotherapy of experimental murine transitional cell carcinoma with glucan and cyclophosphamide. AAALAS Seminar, 24 Aug 83, Southwest Research Foundation, San Antonio, TX. (C)

Lieberman, M.M. Passive mouse protection with antiserum to alginic acid from a mucoid strain of P. aeruginosa. American Society for Microbiology, 6-12 Mar 83, New Orleans, LA. (C)

Lieberman, M.M. Active and passive immunity against Pseudomonas aeruginosa with a ribosomal vaccine and antiserum in C3H/HeJ mice. FASEB, 10-15 Apr 83, Chicago, IL. (C)

Pedersen, C.E., Jr. Guest Lecturer Kirby Junior High School Career Day. 18 Mar 83, Kirby, TX.



DEPARTMENT OF EMERGENCY MEDICINE

Slay, R.D. Coma. Emergency Physicians, Darnall Army Hospital, 4 Apr 83, Fort Hood, TX.

Slay, R.D. Mass casualty. Trauma Symposium Wilford Hall USAF Medical Center, 3 May 83, San Antonio, TX.

Prescott, J.E. Case study in the utilization of a phased response disaster plan. Third World Congress in Emergency and Disaster Medicine, 25 May 83, Rome, Italy.

DEPARTMENT OF MEDICINE

Office of the Chief

Thornsvard, C.T. Clinicopathological conference. USAF Regional Hospital, 5 Jan 83, Carswell AFB, TX.

Allergy Immunology Service

Ramirez, D.A. The natural history of mountain cedar pollinosis. Carl W. Tempel Symposium in Allergy-Immunology and Pulmonary Disease, 26 Jan 83. (C)

Ramirez, D.A. Predicted dose to dose variability in serum theophylline concentrations in patients on Theo-Dur. Carl W. Tempel Symposium in Allergy-Immunology and Pulmonary Disease, 26 Jan 83. (C)

Ramirez, D.A. The natural history of mountain cedar pollinosis. 39th Annual Meeting of the American Academy of Allergy and Immunology. 22 Mar 83, Hollywood, FL. (C)

Cardiology Service

Rubal, B.J. Cardiac dimensional changes associated with jogging and deconditioning in college men. 33rd Annual Meeting of Physiology, Oct 82, San Diego, CA. (C)

Rubal, B.J. Cardiac adaptation associated with physical conditioning. University of California at San Diego, Oct 82, San Diego, CA. (C)

Pasipoularides, A. Fluid dynamics of aortic stenosis: mechanisms of subvalvular gradient generation. 5th Annual Conference of American Society of Biomechanisms. Seattle, WA, Oct 82.

Duster, M.c. Long term follow-up of dysrhythmias following the mustard procedure for transposition. American Academy of Pediatric Cardiology, Oct 82, New York, NY.

Pasipoularides, A. Fluid dynamic mechanisms of subvalvular gradient generation in aortic stenosis. Annual Scientific Sessions of the American Heart Association, 15-18 Nov 82, Dallas, TX.

Murgo, J.P. Impedance of the pulmonary arterial system in normal man: effects of respiration and comparison to systemic impedance. 55th Annual Scientific Sessions of the American Heart Association, 15-18 Nov 82, Dallas, TX. (C)

Pasipoularides, A. Activation-inactivation dynamics and impaired relaxation in hypoxia. 55th Annual Scientific Sessions of the American Heart Association, 15-18 Nov 82, Dallas, TX. (C)

Phillip, D. Effects of sodium nitroprusside infusion in patients with congestive cardiomyopathy. NSCPT Conference, Nov 82, Las Vegas, NV. (C)

Murgo, J.P. Ejection dynamics of obstructive and nonobstructive hypertrophic cardiomyopathy. International Workshop on Hypertrophic Obstructive Cardiomyopathy, Dec 82, Dusseldorf, Germany. (C)

Craig, W.E. Diastolic abnormalities of hypertrophic cardiomyopathy reproduced by asynchrony of the left ventricle in conscious dogs. 32nd Annual Scientific Session, American College of Cardiology, Mar 82, New Orleans, LA. (C)

Rathbun, J.D. Impaired hemodynamic function induced by chronic oral propranolol. 32nd Annual Scientific Session, American College of Cardiology, Mar 82, New Orleans, LA. (C)

Damore, S. Effects of endurance condition on the heart: an echocardiographic study. FASEB, 1 Apr 83, Chicago, IL. (C)

Moody, J.M. Ejection fraction in heart rate-controlled upright bicycle exercise: the cardiac response of endurance athletes. FASEB, 1 Apr 83, Chicago, IL. (C)

Pasipoularides, A. Left ventricular systolic dynamics and intrinsic hydrodynamic loading. FASEB, 1 Apr 83, Chicago, IL. (C)

Rubal, B.J. Phasic respiratory changes in cardiac dimensions by echocardiography in normal subjects and pentathletes. FASEB, 1 Apr 83, Chicago, IL. (C)

Moody, J.M. Heart-rate controlled upright bicycle exercise: ejection fraction response in endurance athletes and normal subjects. Army Association of Cardiology, Eisenhower Army Medical Center, May 83, Augusta, GA. (C)

Miller, J.W. The relationship of systolic anterior movement of the mitral valve to intraventricular pressure gradients and left ventricular outflow in hypertrophic cardiomyopathy. Army Association of Cardiology, May 83, August, GA. (C)

Latham, R. A study of the transmission of the arterial pulse and the effects of reflection in the thoracic and abdominal aorta of man. Army Association of Cardiology, May 83, Augusta, GA. (C)

Craig, W.E. Effects of nifedipine on diastolic function in hypertrophic cardiomyopathy. Army Association of Cardiology, May 83, Augusta, GA. (C)

Bowman, M.A. A study of the relationship between intraventricular systolic gradients and diastolic function in hypertrophic cardiomyopathy. Army Association of Cardiology, May 83, Augusta, GA. (C)

Zumbrun, S.R. Transluminal coronary angioplasty: Initial experience at Brooke Army Medical Center. Army Association of Cardiology, May 83, Augusta, GA. (C)

Geer, M.R. The effects of military anti-shock trousers (MAST) on cardiovascular hemodynamics. Army Association of Cardiology, May 83, Augusta, GA. (C)

Murgo, J.P. Ejection dynamics in HCM - Relationship of outflow murmurs. International Bymposium on Auscultation and Phonocardiography, 18 Aug 83, Kasmir University, India. (C)

Nichols, W.W. Age related changes in ventricular vascular coupling in normal man. Arterial Heart Haemodynamics International Union of Physiological Sciences, XXIX International Congress, Univserity of Sydney, Australia. (C)

Murgo, J.P. Ascending aortic imepdance and pulse wave reflection during Valsalva maneuver in man. Arterial Heart Haemodynamics International Union of Physiological Sciences, XXIX International Congress University of Sydney, Australia, 25 Aug 83. (C)

#### Dermatology Services

Clemons, D.E. Perforating granuloma annulare associated with Henoch-Schonlein purpura. Southern Medical Association, 1 Nov 82, Atlanta, GA.

Salasche, S.J. Histopathology Session. American College of Chemosurgeons Annual Meeting, 2 Dec 82, New Orleans, LA.

Clemons D.E. Histopathology Session. American College of Chemosurgeons Annual Meeting, 2 Dec 82, New Orleans, LA.

Clemons, D.E. Congenital vellus hair cysts. American Academy of Dermatology 41st Annual Meeting, 4 Dec 82, New Orleans, LA.

D'Silva, N. Alopecia mucinosa. American Academy of Dermatology 41st Annual Meeting, 4 Dec 82, New Orleans, LA.

Storm, R.M. Perforating granuloma annulare associated with Henoch-Schonlein purpura. American Academy of Dermatology 41st Annual Meeting, New Orleans, LA, 4 Dec 82.

Lewis, C.W. The effect of exchange transfusions on prophyras. American Academy of Dermatology 41st Annual Meeting, 5 Dec 82, New Orleans, LA. (C)

Lewis, C.W. Neocytophoresis: new treatment for the hepatic prophyras. American Academy of Dermatology 41st Annual Meeting, 7 Dec 82, New Orleans, LA. (C)

Salasche, S.J. Surgical approach to myxoid cysts of fingernails. American Academy of Dermatology 41st Annual Meeting, 7 Dec 82, New Orleans, LA.

Clemons, D.E. Lennert's lymphoma. South Central Dermatology Meeting, 5 Feb 83, San Antonio, TX

Kraus, E.W. Clinical research at BAMC. South Central Dermatologic Congress, 5 Feb 83, San Antonio, TX.

Clemons, D.E. Histopathology Session. South Central Dermatopathology Course, 25 Feb 83, San Antonio, TX.

Clemons, D.E. Lymphomatoid granulomatosis eventuating into Lennert's lymphoma. South Central Dermatopathology Course, 26 Feb 83, San Antonio, TX.

Lewis, C.W. The porphyrias: new modality of therapy. Dermatology Symposium, 5 Apr 83, Scottsdale, AZ. (C)

Lewis, C.W. Miliaria and tropical anhidrotic asthenia. Dermatology Symposium, 5 Mar 83, Scottsdale, AZ.

Lewis, C.W. Warm water immersion foot. Dermatology Symposium 6 Mar 83, Scottsdale, AZ.

Salasche, S.J. Efficacy of electrodesiccation and curettage of mid-face basal cell carcinoma. American Society of Dermatology Serugery, 26 Mar 83, Williamsburg, VA. (C)

Lewis, C.W. Use of red cell exchange and plasmapheresis in treatment of porphyria. Harvard Massachusetts General Hospital, 13 May 83, Boston, MA. (C)

Lewis, C.W. Toxic chemical agents. Preventive Medicine Course, 25 May 83, AHS, Fort Sam Houston, TX.

Lewis, C.W. Dermatology in a combat environmens. Six lectures given to C-4 Course, Apr-Jun 83, Camp Bullis, TX.

Salasche, S.J. Gems and pearls for the dermatologic surgeon. 8th Annual Uniformed Services Dermatology Seminar, 19 May 83, Colorado Springs, CO.

#### Endocrinology Service

Martodam, R., Taylor, T.J. Intravenous Etidronate Disodium (EHDP) for the treatment of hypercalcemia of malignancy. 13th International Annual Cancer Congress, Aug 83, Vienna, Austria. (C)

Taylor, T.J. Periodic paralysis. Endocrine Clinical Conference, Oct 82, University of Texas Health Science Center at San Antonio (THSCSA), San Antonio, TX.

Georgitis, W.J. Primary lymphoma of the thyroid. Endocrine Clinical Conference, UTHSCSA, 14 Oct 82, San Antonio, TX.

Taylor, T.J. Hyperlipidemia. BAMC Satellite TV Lecture, 6 Jan 83, Fort Sam Houston, TX.

Georgitis, W.J. Myasthenia gravis and primary gonadotropin resistant ovary syndrome. Endocrine Clinical Conference, UTHSCSA, 21 Apr 83, San Antonio, TX.

Georgitis, W.J. Graves' disease. BAMC Satellite TV Lecture, 5 Aug 83, Fort Sam Houston, TX. (C)

#### Hematology-Oncology Service

Cowan, J.D. The comparative antitumor activity of Adriamycin, Mitoxantrone and Bisantrene in human breast cancer as measured by a cloning assay. 5th Annual San Antonio Breast Cancer Symposium, 5-6 Nov 82, San Antonio, TX. (C)

Sandbach, J., Cowan, J.D. Bisantrene, an active drug in breast cancer selected by screening in the cloning assay. 5th Annual San Antonio Breast Cancer Symposium, 5-6 Nov 82, San Antonio, TX. (C)

McCracken, J.D. Southwest Oncology Group experience with 5-fluorouracil in carcinoma of the colon. 13th International Congress of Chemotherapy, Sep 83, Vienna, Austria. (C)

#### Infections Disease Service

Hawkes, C.A. Experimental model of amebiasis. Infectious Disease Section, UTHSCSA, 15 Jun 83, San Antonio, TX.

McAllister, C.K. Antimicrobial therapy - 1983. San Antonio Chest Hospital, 28 Jun 83, San Antonio, TX.

#### Nephrology Service

Saylor, R.P. Is chronic plumbism important in pathogenesis of renal disease in gout? 15th Annual Meeting of American Society of Nephrology, 12-14 Dec 82, Chicago, IL.

#### Neurology Service

McFarling, D.A. Current concepts in language: the role of the right hemisphere. 3rd Annual AMEDD Neurology Conference, Nov 82, Letterman Army Medical Center, CA.

McFarling, D.A. Leonard Wood, Harvey Cushing, and traumatic meningiomas. Society of Clinical Neurology, Oct 82, Lake of the Ozarks, MO.

#### Pulmonary Disease Service

Matthews, J.I. Pulmonary problems. 6-A-F4 Armed Forces Entrance Medical Examiners Course, Fort Sam Houston, TX.

Ewald, F.W. Nifedipine does not alter methacholine-induced bronchial reactivity. 35th Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, 25 Jan 83.

Aldarondo, S. Drug resistant pattern of mycobacterium tuberculosis in South Texas. 35th Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, 24 Jan 83.

Ritchey, H.M. BAMC experience with CT scanning in staging carcinoma of the lung. 35th Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology, Fitzsimons Army Medical Center, 24 Jan 83.

Bush, B.A. Blood gas laboratory quality control. 35th Annual Carl W. Tempel Symposium on Pulmonary Disease and Allergy-Immunology. Fitzsimons Army Medical Center, 24 Jan 83.

Matthews, J.I. Nifedipine does not alter methacholine-induced bronchial reactivity. Annual Meeting of the American Thoracic Society, 8-11 May 83, Kansas City, Mo. (C)

#### Rheumatology Service

Via, C.S. Immune complex--positive sera directly stimulate polymorphonuclear leukocyte oxygenation activity but inhibit the oxygenation response to a secondary stimulus. Third International Conference on Superoxide and Superoxide Dismutase III, 3-7 Oct 82, New York, NY. (C)

Via, C.S. The use of chemiluminescence in the detection of immune complexes. American Society for Microbiology, 7 Mar 83, New Orleans, LA. (C)

Via, C.S. Fatigue of human polymorphonuclear leukocyte (PMNL) oxygenation activity induced by immune complex (IC) positive lupus erythematosus (SLE) serum. 47th Annual Meeting of the American Rheumatism Association, 1-4 Jun 83, San Antonio, TX.

#### DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

Capen, C.V. Malignancy of the vulva experienced at the University of Kansas Medical Center. Armed Forces District Meeting of Obstetrics and Gynecology, Oct 82, Portland OR.

Wallace, R.L. Delivery method of very low birth weight infants: cesarean section versus vaginal delivery. Armed Forces District Meeting of Obstetrics and Gynecology, Oct 82, portland, OR. (C)

Wallace, R.L. Prophylactic antibiotic therapy in emergency cesarean sections. Armed Forces District Meeting of Obstetrics and Gynecology, Oct 82, Portland, OR.

Capen, C.V. Evaluation of operative risk of the elderly patient. Conference on Gynecologic Surgery, Nov 82, Louisville, KY.

Capen, C.V. Staples in surgery, a review. Conference on Gynecologic Surgery, Nov 82, Louisville, KY.

Capen, C.V. Menopause. Invited Lecturer, UTHSCSA, 15 Dec 82, San Antonio, TX.

Capen, C.V. Enterovaginal and colovaginal fistulae: etiology and treatment. American College of Surgeons SW Chapter, Jan 83, San Antonio TX.

Wallace, R.L. External cephalic version of tocolysis: observations and a continuing experience at LAC/USC Medical Center. Society of Perinatal Obstetricians, Jan 83, Los Angeles CA.

Wallace, R.L. The route of delivery of very low birth weight infants. Society of Perinatal Obstetricians, Jan 83, Los Angeles, CA.

Wallace, R.L. Extraperitoneal cesarean section - a surgical form of infection prophylaxis. Society of Perinatal Obstetricians, Jan 83, Los Angeles, CA.

Wallace, R.L. Amnionitis - optimal operative management: extraperitoneal cesarean section versus low cervical transperitoneal cesarean section. Society of Perinatal Obstetricians, Jan 83, Los Angeles, CA.

Capen, C.V. Gastrointestinal surgery in gynecology. Texas Tech School of Medicine, 3 May 83, El Paso TX.

Capen, C.V. Laser surgery in gynecology. Texas Tech School of Medicine, 3 May 83, El Paso, TX.

#### DEPARTMENT OF PATHOLOGY AND ALS

##### Clinical Pathology

Perez, T. Evaluation of virocult - a self-contained viral collection and transportation system using a reference laboratory population. International Symposium on Medical Virology, 2-4 Dec 82, Anaheim CA. (C)

Perez, T. Evaluation of virocult - a self-contained viral collection and transportation system using a reference laboratory population. Texas Branch, American Society for Microbiology, Mar 83, Houston, TX. (C)

Juchau, S.V. Clinical evaluation of the new AMS GSC plus card. Texas Branch, American Society for Microbiology, Mar 83, Houston, TX. (C)

Perez, T. Evaluation of virocult - a self-contained viral collection and transportation system using a reference laboratory population. Society of Armed Forces Medical Laboratory Scientists (SAFMLS), Mar 83, San Antonio, TX. (C)

Nauscheutz W. Clinical Evaluation of the new AMS GSC plus card. SAFMLS, Mar 83, San Antonio, Tx. (C)

Harrison, L. Specificity, sensitivity, and prediction values of gonozyme detection kits. SAFMLS, Mar 83, San Antonio, TX.

Juchau, S.V. Biotyping of Haemophilus influenzae using the AMS EBC plus card. American Society of Microbiology, 6 Mar 83, New Orleans, LA.

Nauscheutz, W. Virology outside the medical center workshop. SAFMLS, Mar 83, San Antonio, TX.

Nauscheutz, W. Clinical evaluation of the new AMS GSU card. SAFMLS, Mar 83, San Antonio, TX.

Rowen, J.W. Comparison of the API STAPH-IDENT system and the AntiMicrobic system gram positive identification card for the identification of staphylococci. American Society for Microbiology, 6 Mar 83, New Orelans, LA.

#### Veterinary Lab Service

Gray, M. R. Leptospirosis among military personnel in training in Panama. University of Massachusetts, 17 Aug 82, Amerherst, MA. (C)

Gray, M.R. Leptospirosis - laboratory service support to the OTSG research mission. Current Trends in Veterinary Laboratory Operations, Fort Sam Houston, TX.

Gray, M.R. Microbiology proficiency program. Current Trends in Veterinary Laboratory Operations, Fort Sam Houston, TX.

Gray, M.R. Serological studies on leptospirosis, Workshop II. Walter Reed Army Institute of Research, 2 Mar 83, Washington, DC.

#### DEPARTMENT OF PEDIATRICS

Parry, W.H. Microcomputer graphing of neonatal data. Second Symposium on Computers in Perinatal Medicine, 24-26 May 82, Cleveland, OH.

Gold, L.F. Maternal psychosocial functioning in families of very low birth-weight infants. Southwestern Psychological Association, 14-16 Apr 83.

Skarin, R. Demonstration of computer application in perinatal medicine. Eighth Annual Conference on Neonatal Perinatal Medicine, 26-28 May 83, Santa Fe, NM.

Skarin, R. Demonstration of computer application in perinatal medicine. Fitzsimons Army Medical Center, 26-30 Jun 83.

Takao, R. Approach to the adolescent. NEISD, Secondary Shool Inservice for Teachers, 25 Aug 83, San Antonio, TX.

Nalle, L. Thermoregulation, bilirubin, and gestational aging in newborns. ICU Nurses Course, Fort Sam Houston, TX.

Parry, W.H. Fiberoptic bronchoscopy and diagnosis of congenital stridor. Pediatric and Family Practice Staff and Housestaff, 28 Sep 83, Fort Benning, GA.

#### DEPARTMENT OF PSYCHIATRY

Hopewell, C.A. Serial neuropsychological evaluation in a case of reversible electrocution encephalopathy. AMEDD Psychology Symposium 13-15 Nov 82, August, GA.



Hopewell, C.A. Hemichorea - hemiballismus as conversion reaction following closed head injury. Annual Convention of the Texas Psychological Association, 3-6 Nov 82, Dallas, TX.

Hopewell, C.A. Current trends in neuropsychology. Annual Convention of the Texas Psychological Association, 3-6 Nov 82, Dallas, TX.

Stave, J. A rationale for family therapy with military populations. AMEDD Psychology Symposium, 13-15 Nov 82, Augusta, GA.

Gillooly, D.H. Psychological effects of soldier high altitude exposure: study program report. AMEDD Psychologists' Conference, 15 Nov 82, Augusta, GA.

Gillooly, D.H. Community mental health activity at US Army Medical Activity documenting health care service advances by local trend summary reports. AMEDD Psychologists' Conference, 18 Nov 82, Augusta, GA.

Gillooly, D.H. Multiple challenges of Army Medical Department psychologists: Health Services Command Consultant Appraisal and Summary. AMEDD Psychologists' Conference, 19 Nov 82, Augusta, GA.

#### DEPARTMENT OF RADIOLOGY

Bunker, S.R. Fourier phase analysis in patients with severely compromised ventricular function. 7th Western Regional Meeting of the Society of Nuclear Medicine, 7-10 Oct 82, San Diego, CA.

Hartshorne, M.F. Fourier phase analysis in non-cyclic dynamic studies. 7th Western Regional Meeting of the Society of Nuclear Medicine, 7-10 Oct 82, San Diego, CA.

Janaki, L.M. Orbital irradiation for dysthyroid orbitopathy. American Academy of Ophthalmology, 4 Nov 82, San Francisco, CA.

Karl, R.D., Jr. Guest Lecturer in Physical Therapy-OT Management Course, School of Health Care Sciences, 17-18 Nov 82, Sheppard, AFB, TX.

Fritz, A.L. Hang-up of contrast material: a sign of carotid ulceration. Radiological Society of North America Annual Meeting, 27 Nov - 3 Dec 82, Chicago, IL.

Huggins, M.J. Low dose streptokinase and angioplasty in occlusive disease. 10th Annual Vascular Surgery Seminar, Uniformed Services University of Health Sciences, 2-3 Dec 82, Bethesda, MD.

Baikadi, M. Interstitial dosimetry using CT scan in the treatment of primary breast cancer. American Endocurietherapy Society, 8-10 Dec 82, Key Biscayne, FL.

Baikadi, M. Treatment of lip carcinoma with  $^{192}\text{Ir}$  implant. American Endocurietherapy Society, 8-10 Dec 82, Key Biscayne, FL.

Brown, C.W. Head and body CT imaging: an overview. McKenna Memorial Hospital, 17 Feb 83, New Braunfels, TX.

Janaki, L.M. Breast cancer - should the patient become involved in treatment choice. San Pedro Hills Women's Club, 2 Mar 83, San Antonio, TX.

Janaki, L.M. Early breast cancer - minimal surgery and curative radiation therapy. Brookhollow Women's Club, 15 Mar 83, San Antonio, TX.

Cable, H.F. Ultrasonographic characterization of ovarian neoplasm: the spectrum of disease. Hospital de Seguro Sociale, 9 Mar 83, Panama City, Panama.

Cable, H.F. CT of abdominal neoplasms: an overview and update. Hospital de Seguro Sociale, 9 Mar 83, Panama City, Panama.

Cable, H.F. CT abdominal neoplasia - an overview. McKenna Memorial Hospital, 17 Mar 83, New Braunfels, TX.

Hartshorne, M.F. Thallium tomography and fourier analysis in nuclear cardiology. Social Security Hospital for Cardiology and Pulmonary, 29 Apr 83, Mexico, D.F.

Hartshorne, M.F. MDS A<sup>2</sup> practical exercises and workshop in cardiovascular nuclear medicine. Social Security Hospital for Cardiology and Pulmonary, 29 Apr 83, Mexico, D.F.

Hartshorne, M.F. Cardiovascular Nuclear Medicine overview. Mexican Nuclear Medicine Society, 30 Apr 83, Cuernavaca, Mex.

Bunker, S.R. Diagnostic nuclear cardiology. Mad River Community Hospital, 28 Apr 83, Arcata, CA.

Bunker, S.R. Selective intra-arterial digital angiography: an outpatient procedure. Harvard Medical School, 13-17 Jun 83, Boston MA.

Janaki, L.M. Brooke's experience with limited surgery and curative radiation therapy in carcinoma of breast. 6th Annual Symposium on Breast Cancer, Apr 83, San Antonio, TX.

Ramirez, H., Jr. ARRS - Arthrotomography: a valuable technique in the assessment of joint disease. American Roentgen Ray Society, Apr 83.

Fritz, A.L. Interventional techniques in radiology. AMEDD Walter Reed Radiology Conference, 25-27 May 83, Washington, DC.

Bunker, S.R. Selective intra-arterial digital angiography. Department of Radiology, Creighton University and St. Joseph Hospital, Aug 83, Omaha, NE.

Bunker, S.R. Gastrointestinal nuclear medicine. San Antonio Nuclear Medicine Society, Aug 83, San Antonio, TX.

Bunker, S.R. US Army Nuclear Medicine technologist review course. Letterman Army Medical Center, Sep 83, Presidio of California, San Francisco, CA.

Bunker, S.R. Application of Fourier phase analysis in exercise gated blood pool examinations. Society of Nuclear Medicine Medley, Missouri Valley Chapter, Sep 83, Omaha, NE.

## DEPARTMENT OF SURGERY

### Anesthesia and Operative Service

Baysinger, C.L. Evaluation of neurotoxicity of local anesthetics following subarachnoid injection. American Society of Anesthesiologists, 22-26 Oct 82, Las Vegas, NE.

Baysinger, C.L. Anesthetic considerations of valvular heart disease. TV Satellite Presentation, 25 Apr 83, Fort Sam Houston, TX.

Reynolds, W.J. Physiology of epidural anesthesia. Annual Advanced Anesthesia Nursing Practice Course, 9 May 83, Washington, DC.

Middaugh, R.E. A clinical study of the benefits of Ketamine for cesarean section. Society of Obstetric Anesthesiologists and Perinatologists, 26 May 83, Vancouver, BC, Canada.

Baumgarten, R.K. One lung anesthesia. TV Satellite Presentation, 11 Jul 83, Fort Sam Houston, TX.

Middaugh, R.E. CPR training. Boy Scout Troop #285, Coker United Methodist Church, 20 Aug 83, San Antonio, TX.

Middaugh, R.E. IV fluid management in the operating room environment. National IV Therapy Association, 8 Sep 83, San Antonio, TX.

Middaugh, R.E. Anesthetic nursing considerations for the pediatric patient in the operating room. National Association of Operating Room Nurses, 17 Sep 83, San Antonio, TX.

### Cardiothoracic Surgery

Schuchmann, G.F. Moderator, Clinical Session on Cardiac Trauma. First Annual USUHS Thoracic Surgery Symposium, 2 Oct 82, Bethesda, MD.

Schuchmann, G.F. Blunt and penetrating injuries of the heart. Eisenhower Army Medical Center, 4 Nov 82, Augusta, GA.

Schuchmann, G.F. Bacterial endocarditis with mitral regurgitation and mycotic aneurysm of the abdominal aorta, the hepatic artery, and the left subclavian artery. 19th Annual Session of Society of Thoracic Surgery, 18 Jan 83.

Schuchmann, G.F. The clinical management of coexistent acute bacterial endocarditis and multiple mycotic aneurysms. Air Force Clinical Surgeons Symposium, 4 May 83, San Antonio, TX.

Schuchmann, G.F. Management of patient with coexistent coronary artery and peripheral vascular disease. Western Washington Cardiovascular Disease Symposium, 19 May 83, Tacoma, WA.

Schuchmann, G.f. A potpourri of vexing and interesting cardiac surgery cases. Western Washington Cardiovascular Disease Symposium, 21 May 83, Tacoma, WA.

Schuchmann, G.F. The surgical management of injuries of the heart. Western Washington Cardiovascular Disease Symposium, 20 May 83, Tacoma, WA.

Peake, J.B. Sternal dehiscence - early and late. Association of Army Cardiology, Eisenhower Army Medical Center, May 83, Augusta, GA.

Helsel, R.A. Cardiac surgery and chronic dialysis patients. Association of Army Cardiology, Eisenhower Army Medical Center, May 83, Augusta, GA.

Bowman, G. A. Appendiceal carcinoid. Southwest Surgical Conference, May 83, Mesa, AZ.

Briggs, R.M. Management of cystosarcoma phylloides. TV Satellite Presentation, 22 Aug 83, Fort Sam Houston, TX.

Cohen, D.J. Carcinoma of the esophagus. Visiting professor St. Mary's Hospital, 19 Sep 83, Waterbury, CT.

#### General Surgery Service

Walters, M.J. Longterm venous access for chemotherapy. Pediatric Oncology Group, Oct 82, Washington, DC.

Collins, G.J., Jr. Cerebrovascular Insufficiency. San Antonio Surgical Society, Oct 82, San Antonio, TX.

Collins, G.J., Jr. Management of venous disorders. ACS Symposium on General Surgery and Trauma, Nov 82, Spartanburg, SC.

Briggs, R.M. Cystosarcoma phylloides. Controversies in Breast Cancer, M.D. Anderson Tumor Institute, Nov 82, Houston, TX.

Collins, G.J., Jr. Coexistent cerebral and cardiac ischemia. Military Vascular Surgeons Meeting, Dec 82, Bethesda, MD.

Briggs, R.M. Cystosarcoma phylloides. South Texas Chapter, American College of Surgeons, Jan 83, San Antonio, TX. BEST RESIDENT PAPER

Wesen, C. Breast abscess. South Texas Chapter, American College of Surgeons, Jan 83, San Antonio, TX.

Hamelink, J. Prostatism and inguinal hernia. South Texas Chapter, American College of Surgeons, Jan 83, San Antonio, TX. (C)

Walters, M.J. Burn management. Medical Red Flat, Clark AFB, Phillipines, Feb 83.

Smith, A. The burned hemophiliac. American Burn Association, May 83, New Orleans, LA.

Briggs, R.M. Vascular injury to the major branches of the aortic arch. Gary P. Wratten Surgical Symposium, Mar 83, Augusta, GA.

Collins, G.J., Jr. Management of arterial and prosthetic infections. Gary P. Wratten Surgical Symposium, Mar 83, Augusta, GA.

Hamelink, J. Septic thrombophlebitis - the BAMC experience. Gary P. Wratten Surgical Symposium, Mar 83, Augusta, GA.

Rosenthal, D. Liver trauma, UTHSCSA Surgical Journal Club, 2 Mar 83, San Antonio, TX.

Briggs, R.M. Cystosarcoma phylloides. Joe Baugh Resident Paper Contest, USUHS, Apr 83, Bethesda, MD. FIRST PRIZE

Clary, R. Changing trends in gastric carcinoma. William Beaumont Gastrointestinal Symposium, Apr 83, El Paso, TX.

Solla, J.A. Diagnostic peritoneal lavage. BAMC Trauma Symposium, 9 Apr 83, Fort Sam Houston, TX.

Collins, G.J., Jr. Phleborheogram in diagnosis of venous obstruction. Spring Meeting, American College of Surgeons, Apr 83, Washington, DC.

Rosenthal, D. Modern diagnosis and manabement of lower intestinal bleeding. Capital Hospital, 19 Apr 83, Beijing, China.

Rosenthal, D. Modern diagnosis and management of lower intestinal bleeding.. Liaoning Tumor Hospital and Institue, 23 Apr 83, Shenyang, China.

Rosenthal, D. Management of colorectal trauma. Annual USAREUR Medical-Surgical Conference, 11 May 83, Garmish, Germany.

Rosentahl, D. Soft tissue and vascular injuries associated with pelvic fractures. USAREUR Medical-Surgical Conference, 11 May 83, Garmish, Germany.

Rosenthal, D. Management of common anorectal problems. USAREUR Medical-Surgical Conference, 12 May 83, Garmish, Germany.

Collins, G.J., Jr. Coexistant cardiac and cerebrovascular insufficiency. Southwest Surgical Congress, 2-5 May 83, Phoenix, AZ.

Kunkel, J. Ileocecal syndrome. Southwest Surgical Congress, 2-5 May 83, Phoenix, AZ.

Gomez, E. Wound hematomas after carotid srugery. Southwest Surgical Congress, 2-5 May 83, Phoenix, AZ.

Briggs, R.M. Cystosarcoma phylloides. Southwest Surgical Congress, 2-5 May 83, Phoenix, AZ.

Briggs, R.M. Anastomotic false aneurysms. Southwest Surgical Congress, 2-5 May 83, Phoenix, AZ.

Walters M.J. Burn management. Medical Red Flat Progarm, Sheppard, AFB, TX, 9-14 Jun 83.

Wesen, C. Tc<sup>99</sup> tagged RBC's in diagnosis of intestinal bleeding. American Society of Colon and Rectal Surgeons, 6 Jun 83, Boston, MA.

Collins, G.J., Jr. Arterial and prosthetic graft infections. Peripheral Vascular Surgical Club, Jun 83, San Francisco, CA.

Rosenthal, D. Management of commonly seen anorectal disease. Panama MEDDAC, 14 Sep 83.

Solla, J.A. Peritoneal lavage in trauma, the BAMC experience. West Covina Hospital Trauma Symposium, 24 Sep 83, West Covina, CA.

#### Neurosurgery Service

Harris, R.D. Brooke formula for management of head injuries. Congress of Neurological Surgeons, Oct 82, Toronto, Canada.

Harris, R.D. NAD metabolism in cultured human pituitary cells. Congress of Neurological Surgeons, Oct 82, Toronto, Canada.

Blumenkopf, B. Neuropeptide localization in the feline spinal cord following nerve root avulsion injury. American Pain Society Third General Meeting, 29 Oct 82, Miami Beach, FL.

Blumenkopf, B. Dorsal horn neuronal activity after unilateral lumbar root avulsion in the cat. American Pain Society Third General Meeting, 30 Oct 82, Miami Beach, FL.

Harris, R.D. Head trauma to rapid deployment force. Fort Campbell, KY., 17 Nov 82.

Harris, R.D. Spinal injuries to rapid deployment force. Fort Campbell, KY., 10 Dec 82.

Harris, R.D. Pituitary tumors. Association of Neurosurgical Nurses, Methodist Hospital, 16 Feb 83, San Antonio, TX.

Harris, R.D. Head injury. Medical Staff Conference, Blanchfield Army Community Hospital, 25 Feb 83, Fort Campbell, KY.

Harris, R.D. Brain death. Southwest Texas Organ Bank, 4 Mar 83, San Antonio, TX.

Blumenkopf, B. Neuropeptide localization in the feline spinal cord following nerve root avulsion injury. American Association of Neurological Surgeons 51st Annual Meeting, 25 Apr 83, Washington, DC.

#### Ophthalmology Service

Bode, D. Trauma. Physicians Assistants National Meeting, 9 Nov 82, San Antonio, TX.

Board, R.J. Vertical strabismus and restrictive strabismus. Visiting Lecturer, UTHSCA, 30 Nov 82, San Antonio, TX.

Zervas, J.P. Permanent visual field defects in migraines. Bascom Palmer Eye Institute, 4 Dec 82, Miami, FL.

Griffith, D. Fluorescein Angiography. Invited Lecturer, UTHSCSA, 4 Feb 83 San Antonio, TX.

Board, R.J. Kawasaki's disease. Invited Lecturer, UTHSCSA, 10 Feb 83, San Antonio, TX.

Bode, D. Conjunctivitis. Invited Lecturer, UTHSCSA, 3 Mar 83, San Antonio, TX.

O'Hara, M. Ocular complications of anti-neoplastic agents. Tripler AMC, HI, 23 Feb 83.

Griffith, D.G. Inflammatory pigment epithelial observations. Ophthalmology Conference, UTHSCSA, 15-16 Apr 83, San Antonio, TX.

Bode, D. S. epidermidis endophthalmitis. Ophthalmology Conference, UTHSCSA, 15-16 Apr 83, San Antonio, TX.

Board, R.J. Adjustable suture techniques. Ophthalmology Conference, UTHSCSA, 15-16 Apr 83, San Antonio, TX.

Gearhart, J.R. Automating the Farnsworth 100 hue techniques. Ophthalmology Conference, UTHSCSA, 15-16 Apr 83, San Antonio, TX.

Hollsten, D. Choroidal melanoma. Ophthalmology Conference, UTHSCSA, 15-16 Apr 83, San Antonio, TX.

Zervas, J. Unilateral Nystagmus. Ophthalmology Conference, UTHSCSA, 15-16 Apr 83, San Antonio, TX.

Coronado, T. Neovascularization. Ophthalmology Conference...15-16 Apr 83...

Davitt, W. Drift in postoperative intermittent exotropes. Ophthalmology Conference...15-16 Apr 83...

Cheung, D. Herpes keratitis. Ophthalmology Conference...15-16 Apr 83...

Lloyd, W. Lacrimal sac tumors. Ophthalmology Conference...15-16 Apr 83...

Gagliano, D. Neovascular glaucoma. Ophthalmology Conference...15-16 Apr 83...

O'Hara, M.A. Isolated VI nerve palsy. Ophthalmology Conference...15-16 Apr 83...

Milne, H.L. Repair of cyclodialysis cleft. Ophthalmology Conference...15-16 Apr 83...

Knapp, W.B. Use of computer in diagnosing ocular pathology. American Optometric Association, 28 Jun 83, Washington, DC.

Griffith, D. Retinal dystrophies. University of Kansas, 7 Sep 83, Kansas City, KA.

Griffith, D. Pigment epithelial dystrophies. Kansas City Ophthalmology Society, 7 Sep 83, Kansas City, KA.

#### Orthopaedic Service

Nash, W.C. Transcondylar talar dome fractures. Southern Medical Association, 30 Oct-2 Nov 82, Atlanta, GA.

Nash, W.C. Neer reconstruction of the shoulder. Society of Military Orthopaedic Surgeons, 7-12 Nov 82, El Paso TX.

Williams, S.M. Late total joint infections of dental origin. Society of Military Orthopaedic Surgeons, 7-12 Nov 82, El Paso, TX.

Santos, M.A. The use of the Alexander view in acromioclavicular joint injuries. Society of Military Orthopaedic Surgeons 7-12 Nov 82, El Paso, TX.

Santos, M.A. Treatment of the child with congenital hip dislocation. Society of Military Orthopaedic Surgeons 7-12 Nov 82, El Paso TX.

Dreher, G.F. Scoliosis - the BAMC approach. Society of Military Orthopaedic Surgeons, 7-12 Nov 82, El Paso, TX.

Kouba, S.H. A modified flexor tendon dynamic postoperative rehabilitation orthosis. Society of Military Orthopaedic Surgeons, 7-12 Nov 82, El Paso, TX.

Bucknell, A.L. Anterior and posterior arthrodesis of the spine - when and how. Symposium on Children Orthopaedics, 2-4 Feb 83, Fitzsimons Army Medical Center.

Spires, T.D. Verbelyi-Ogston club foot fracture. American Academy of Orthopaedic Surgeons, 7-15 Mar 83, Anaheim, CA.

Markey, K.L. Prevention of brachial plexus injuries in football athletes. American Academy of Orthopaedic Surgeons, 7-15 Mar 83, Anaheim, CA.

Bucknell, A.L. Adolescent spondylolisthesis. American Academy of Orthopaedic Surgeons, 7-15 Mar 83, Anaheim, CA.

Hawkes, T.A., Jr. Wanted dead or alive - vascular status. Michael Hoke-Hiram Lecture, Scottish Rite Hospital, 29-30 Apr 83, Atlanta, GA.

Nash, W.C. Transcondylar talar dome fractures - not just a sprained ankle. Orthopaedic Residents Conference, Campbell Clinic, 11-14 May 83, Memphis, TN.

Markey, K.L. Common injuries in the occasional athlete. Hidalgo County Medical Society, 8 Sep 83, McAllen, TX.

#### Otolaryngology Service

Harrell, J. Iatrogenic cervical arteriovenous fistula. American Academy of Otolaryngology--Head and Neck Surgery Annual Meeting, Oct 82, New Orleans, LA.



Sawyer, R. Grafts, implants, and late osseous reconstruction after maxillo-facial trauma. Third Annual Maxillofacial Trauma Workshop, U of Texas HSC at San Antonio, American Academy of Facial Plastic and Reconstructive Surgery 7 Nov 82, San Antonio, TX.

Sawyer, R. Cranio-facial tumor surgery. San Antonio Society of Otolaryngology, 19 Apr 83, San Antonio, TX.

Sawyer, R. Use of cranio-facial tumor surgery and myocutaneous flaps and discussion of full use of myocutaneous flaps. Basic Science Course in Otolaryngology, Armed Forces Institute of Pathology, 26 May 83, Washington, DC.

#### Urology Service

Spence, C.R. Most often mismanaged urologic emergencies. Central Texas Physician Assistant Association, Oct 82, San Antonio, TX.

Norbeck, J.C. Lower urinary tract trauma. William Beaumont Army Medical Center Annual Trauma Conference, 20 Nov 82, El Paso, TX.

Norbeck, J.C. The new Army urology medic. 30th Annual Kimbrough Urological Seminar, 28 Nov-3 Dec 82, New Orleans, LA.

Gangai, M. Continuous flow during transurethral resection: an alternate method. Kimbrough Urological Seminar, 28 Nov-3 Dec 82, New Orleans, LA.

Thompson, I. Treatment of childhood bilateral vas transection with cutaneous vasostomy. 30th Annual Kimbrough Urological Seminar, 28 Nov-3 Dec 82, New Orleans, LA.

Hermans, J. Treatment of residual prostatic carcinoma after radical prostatectomy. 30th Annual Kimbrough Urological Seminar, 28 Nov-3 Dec 82, New Orleans, LA.

Bryant, K.R. Partial ureteral obstruction by a retroiliac ureter. 30th Annual Kimbrough Urological Seminar, 28 Nov-3 Dec 82, New Orleans, LA.

Rounder, J.B. Non-operative hydrocele management - role of sclerosing agents. 30th Annual Kimbrough Urological Seminar, 28 Nov-3 Dec 82, New Orleans, LA.

Norbeck, J.C. Adenocarcinoma of the Kidney. TV lecture, 24 Jan 83, Fort Sam Houston, TX.

Gangai, M. Urinary diversion - the why and the when. Principals of Stoma Care Conference, 27 Jan 83, Fort Sam Houston, TX.

Thompson, I. Prostatism and inguinal hernia. South Texas Chapter, American College of Surgeons, 28 Jan 83, San Antonio, TX. (C)

Thompson, I. Prostatism and inguinal hernia. Milam County Medical Society, 15 Feb 83, Rockdale, TX. (C)

Spiegel, R.S. Diagnosis and surgery of UPJ obstruction. TV Lecture .  
2 May 83, Fort Sam Houston, TX.

Ernst, J.J. Cryptorchidism. TV Lecture. 29 Aug 83, Fort Sam Houston, TX.

#### PHARMACY SERVICE

Sikora, R.G. Mobile decentralized unit dose. Pharmacy Management Conference,  
27 May 83, El Paso, TX.

Clyde, B. Preparation of a Pharmacy Service Manpower Survey. Property  
Management Conference, 27 May 83, El Paso, TX.

#### PREVENTIVE MEDICINE AND REHABILITATION SERVICE

Riggan, J. Learning disabled soldier. 1983 ALCD International Conference,  
16-19 Feb 83, Washington, DC.



# Detail Summary Sheet

|  |           |                                     |                            |                                   |         |
|--|-----------|-------------------------------------|----------------------------|-----------------------------------|---------|
| Date:  | 16 Nov 83 | Proj No:                            | C-5-79                     | Status:                           | Ongoing |
| TITLE:   |           |                                     |                            |                                   |         |
| Assessment of Opsonic Capacity and Phagocyte Functionality in Microliter Quantities of Whole Blood |           |                                     |                            |                                   |         |
| Start Date   |           |                                     | 5 Jan 79                   |                                   |         |
| Principal Investigator   |           |                                     | Est Comp Date:             |                                   |         |
| Robert C. Allen, M.D., Ph.D., MAJ, MC  |           |                                     | Facility                   |                                   |         |
| Dept/Sec   |           |                                     | Brooke Army Medical Center |                                   |         |
| Department of Clinical Investigation   |           |                                     | Associate Investigators:   |                                   |         |
| Key Words:   |           |                                     | Michael Peek               |                                   |         |
| Granulocyte  |           |                                     | SP4 Michael Meed           |                                   |         |
| Monocyte   |           |                                     | Gerald Merrill             |                                   |         |
| Chemiluminogenic Probe   |           |                                     |                            |                                   |         |
| Accumulative MEDCASE Cost:   |           | Est Accumulative OMA Cost: \$68,546 |                            | Periodic Review Results: Continue |         |

Objective: To research and develop a rapid, objective, and quantitative approach to the assessment of phagocyte activity in microliter quantities of whole blood by introduction of high quantum yield oxidizable substrate and use of photomultiplication techniques to quantitate chemiluminescence (luminescence resulting from chemical reaction).

Technical Approach: The use of two difficult high quantum yield, oxidizable substrates for quantification of phagocyte  $O_2$ -redox activity in whole blood has been achieved. Luminol, 5-amino-2,3-dihydro-1,4-phthalazinedione, various substituted luminol derivatives, and lucigenin, 10,10'-dimethyl-9,9'-biacridinium dinitrate, have been employed in this manner. Other substrates are also under investigation. A technique for titration of serum opsonic capacity, based on the rate of activation of PMNL  $O_2$ -redox metabolism has also been established using chemiluminogenic probes.

Progress: Chemiluminogenic probing of polymorphonuclear leukocyte and monocyte oxygenation activities is nondestructive, ultrasensitive, and quantifiable. As such, the approach has been modified and applied to the analysis of the kinetics of microbe-specific opsonification by immunoglobulins. The information-effector relationship linking the microbe-specific opsonification capacity of antiserum to effector phagocyte activation is expressed by the derived equation  $L = kD^{-i}$  where  $L$  is the chemiluminescence expressed as peak CL velocity (in photons/min),  $k$  is the proportionality constant,  $D$  is the serum dilution (final volume/initial serum volume), and  $i$  defines the order of the reaction with respect to  $D$ . A similar kinetic approach is being tested for functional assessment of both alternative and classical pathway complement activity in serum.

# Detail Summary Sheet

|   |                            |                    |
|---|----------------------------|--------------------|
| Date: 3 Oct 83  | Proj No: C-8-79            | Status: Terminated |
| TITLE:  |                            |                    |
| The Measurement of Cyclic Nucleotide Levels in Purified Populations of Lymphocytes Incubated with Mitogens. |                            |                    |
| Start Date 6 Feb 79   | Est Comp Date:             |                    |
| Principal Investigator  | Facility                   |                    |
| David G. Burleson, Ph.D., MAJ, MSC  | Brooke Army Medical Center |                    |
| Dept/Sec  | Associate Investigators:   |                    |
| Department of Clinical Investigation  |                            |                    |
| Key Words:  |                            |                    |
| Cyclic nucleotide levels  |                            |                    |
| T and B cells   |                            |                    |
| Mitogens  |                            |                    |
| Accumulative MEDCASE  | Est Accumulative           | Periodic           |
| Cost:   | OMA Cost: \$11455          | Review Results:    |

Objective: To purify guinea pig lymphocytes on density gradients into functional subpopulations and measure intracellular levels of cyclic AMP and cyclic GMP after incubation of the purified cells with the mitogens for T and B Cells.

Technical Approach: Guinea pig lymphocytes are separated on density gradients and further purified by fluorescent activated cell sorting. Cultures from these purified populations are subjected to lectin stimulation and the cultures extracted by acid precipitation at various time periods. Extracts are neutralized, dried over night and reconstituted for purification by cyclic nucleotides by high pressure liquid chromatography (HPLC). Purified extracts are measured by radioimmunoassay. Levels of cyclic AMP and cyclic GMP in stimulated cultures will be compared to unstimulated controls.

Progress: None due to a shortage of available laboratory technician for support of protocol. Therefore, the protocol is terminated until a future date.

# Detail Summary Sheet

|   |          |                |                            |         |            |
|---|----------|----------------|----------------------------|---------|------------|
| Date:   | 3 Oct 83 | Proj No:       | C-38-79                    | Status: | Terminated |
| TITLE: The Effect of Prostaglandin Synthesis Inhibitors on <u>in vitro</u> Suppressor Cell Activity in Lymphocytes from Patients with Common Variable Agammaglobulinemia. |          |                |                            |         |            |
| Start Date  | Sep 79   | Est Comp Date: |                            |         |            |
| Principal Investigator  |          |                | Facility                   |         |            |
| David G. Burleson, Ph.D., MAJ, MSC  |          |                | Brooke Army Medical Center |         |            |
| Dept/Sec  |          |                | Associate Investigators:   |         |            |
| Department of Clinical Investigation  |          |                |                            |         |            |
| Key Words:  |          |                |                            |         |            |
| Agammaglobulinemia  |          |                |                            |         |            |
| T-cell Suppressor   |          |                |                            |         |            |

|                      |                   |                 |
|----------------------|-------------------|-----------------|
| Accumulative MEDCASE | Est Accumulative  | Periodic        |
| Cost:                | OMA Cost:\$12,078 | Review Results: |

Objectives: To test the in vitro activity of prostaglandin synthesis inhibitors, such as indomethacin, on T-cell suppressor activity found in lymphocytes from patients with common variable agammaglobulinemia. The reversal of the suppressing activity on immunoglobulin cells by such inhibitors may indicate candidates for an effective therapeutic drug for this immunodeficiency.

Technical Approach: Human peripheral blood lymphocytes (HPBL) from normal individuals, patients with common variable agammaglobulinemia, or HPBL subjected to a suppressor cell stimulant are incubated in the presence of pokeweed mitogen and selected cultures in the presence of immunomodulating drugs. After six days of culture, the cells are harvested and plated on slides in agar. Immunoglobulin cells are detected using the reverse hemolytic plaque assay. Increased numbers of plaques indicate decreased lymphocyte suppressor activity. Plaque counts of normal patient and suppressor-normal patient cultures are compared to determine the presence of suppressor cell activity. Suppressed cultures incubated with immunomodulating drugs are evaluated for release from suppressor activity. An assay for measuring numbers of suppressor cells and suppressor activity is being developed on the FACS.

Progress: This study is terminated due to insufficient number of patients to study and lack of technical assistance.

# Detail Summary Sheet

|   |  |                             |
|---|--|-----------------------------|
| Date: 3 Oct 83  | Proj No: C-4-80                                | Status: Completed           |
| TITLE:<br>The Development of a <u>Pseudomonas aeruginosa</u> Vaccine for Laboratory Animals, Phase II.  |  |                             |
| Start Date 10 Jan 80  | Est Comp Date:                                 |                             |
| Principal Investigator<br>Michael M. Lieberman, Ph.D., CPT, MSC   | Facility<br>Brooke Army Medical Center         |                             |
| Dept/s c<br>Department of Clinical Investigation  | Associate Investigators:<br>Eleanor Ayala, DAC |                             |
| Key Words:<br><u>Pseudomonas aeruginosa</u><br>Vaccine  |  |                             |
| Accumulative MEDCASE<br>Cost:   | Est Accumulative<br>OMA Cost: \$19,695         | Periodic<br>Review Results: |
| Objective: To develop a safe and effective, multivalent, <u>Pseudomonas aeruginosa</u> vaccine and hyperimmune globulin for laboratory animals. |  |                             |

Technical Approach: Ribosomal vaccines and outer membrane proteins prepared from P. aeruginosa were chemically and physically characterized and analyzed for cross reactions. C3H/HeJ mice, which are refractory to most, if not all, of the biologic effects of lipopolysaccharide (LPS), were used to compare the immunogenicity of purified ribosomes and LPS. Outer membrane protein preparations, which also contain a certain amount of LPS, and phospholipid, were used in the preparation of monoclonal antibodies to P. aeruginosa.

In addition, the alginic acid capsular polysaccharide from a mucoid strain of P. aeruginosa was obtained and antiserum prepared against it. This antiserum was tested for mouse protection alone or in combination with anti-ribosomal serum for a possible synergistic effect.

Progress: Using the C3H/HeJ mouse model, the results showed that ribosomes provided excellent protection against Pseudomonas by both active and passive modes of immunization. LPS provided no protection by either mode of immunization in C3H/HeJ mice. The protection achieved by the ribosomal vaccine cannot be ascribed to a small amount of LPS present in the vaccine. For progress in the preparation of monoclonal antibodies to P. aeruginosa, see progress report C-53-81.

Antiserum to alginic acid was protective as well as anti-ribosomal serum against a mucoid strain of P. aeruginosa. However, a synergistic effect was not observed.

# Detail Summary Sheet

Date: 3 Oct 82 Proj No: C-4-81 Status: Ongoing

## TITLE:

Chemiluminescence (CL) in Populations of Immunocompetent Cells.

|                                      |          |                               |              |
|--------------------------------------|----------|-------------------------------|--------------|
| Start Date                           | 4 Feb 81 | Est Comp Date:                | Undetermined |
| Principal Investigator               |          | Facility                      |              |
| David G. Burleson, Ph.D., MAJ, MSC   |          | Brooke Army Medical Center    |              |
| Dept/Sec                             |          | Associate Investigators:      |              |
| Department of Clinical Investigation |          | Robert C. Allen, M.D., Ph.D., |              |
| Key Words:                           |          | MAJ, MC                       |              |
| Chemiluminescence                    |          | John H. Sinegal, SSG          |              |
| Immunocompetent cells                |          | George Vaughn, DAC            |              |

|   |                    |                 |
|---|--------------------|-----------------|
| Accumulative MEDCASE  | Est Accumulative   | Periodic        |
| Cost:   | OMA Cost: \$12,810 | Review Results: |
| Objectives: To quantitate the oxidative metabolic response of stimulated populations of immunocompetent cells isolated from mouse or guinea pig spleen, thymus, liver, and lymph nodes using chemilumigenic probes. |                    |                 |

To quantitate and characterize the chemiluminescent response from various populations of immunocompetent cells in the presence of cyanide, superoxide dismutase, and catalase.

Technical Approach: Peritoneal cells from guinea pigs injected IP with sodium caseinate are harvested at 7 days. Macrophages (MP) and granulocytes (GL) are separated after centrifugation on Percoll density gradients. The purified cells are incubated with various chemical, lectin, and phagocytic stimulants and several metabolic inhibitors and scavenger enzymes. The resulting activity is measured by chemiluminogenic probe technique. Luminol and DBA are used as probes, and the resulting chemiluminescence is measured in single photon counters. Cell oxygenation activity is also measured by flow cytometry using dichlorofluorescein diacetate as an internal probe. Results obtained by this technique and the chemiluminescent techniques are evaluated.

Progress: A thorough evaluation of the stimulation of late acute phase peritoneal phagocytes has been accomplished. As with human peripheral granulocytes, guinea pig peritoneal phagocytes have good CL activity when stimulated by PMA, opsonified zymosan and several lectins. Significant differences were found between the activity of MP and GL in terms of magnitude and susceptibility to inhibition by metabolic inhibitors and scavenger enzymes. The ability of cells with buoyant density intermediate between MP and GL to inhibit the activity of the two phagocytes is also being investigated. Preliminary experiments indicate the new flow cytometry technique of measuring oxygenation activity shows great promise.



# Detail Summary Sheet

|  |                                       |                       |                            |         |         |
|--|---------------------------------------|-----------------------|----------------------------|---------|---------|
| Date:  | 12 Oct 83                             | Proj No:              | C-13-81                    | Status: | Ongoing |
| TITLE: Therapeutic Manipulation of Metabolic Endocrine Controls During Infection |                                       |                       |                            |         |         |
| Start Date   | 11 Mar 81                             | Est Comp Date: Aug 84 |                            |         |         |
| Principal Investigator   | James H. Anderson, Jr., M.D., LTC, MC |                       | Facility                   |         |         |
| Dept/Sec   | Department of Clinical Investigation  |                       | Brooke Army Medical Center |         |         |
| Key Words:   | Metabolic endocrine controls          |                       | Associate Investigators:   |         |         |
|  | Infection                             |                       | Gerald A. Merrill, DAC     |         |         |

|  |                   |                 |
|--|-------------------|-----------------|
| Accumulative MEDCASE   | Est Accumulative  | Periodic        |
| Cost:  | OMA Cost: \$4,613 | Review Results: |
| Objective: To clearly define the mechanisms of hormonal action and metabolic alterations in infectious disease and thus establish the best therapeutic and supportive care for personnel exposed to infectious agents. |                   |                 |

Technical Approach: Animals with a variety of induced infections will be studied for glucose tolerance and insulin secretion, binding and effects as well as specific biochemical and physiological function of the islets of Langerhans and cellular insulin receptors on monocytes, hepatocytes and adipocytes. In addition, lipid and protein breakdown and metabolism will also be evaluated.

Progress: Continuation of this study at BAMC awaits completion of the laboratory animal facility.

# Detail Summary Sheet

|  |                            |                   |
|--|----------------------------|-------------------|
| Date: 12 Oct 84  | Proj No: C-14-81           | Status: Completed |
| TITLE: Investigation of the Involvement of Endogenous Opiates in the Development of the Metabolic Pathophysiology of Infection and Endotoxin Shock |                            |                   |
| Start Date 11 Mar 81   | Est Comp Date:             |                   |
| Principal Investigator   | Facility                   |                   |
| James H. Anderson, Jr., M.D., LTC, MC  | Brooke Army Medical Center |                   |
| Dept/Sec   | Associate Investigators:   |                   |
| Department of Clinical Investigation   | Gerald A. Merrill, DAC     |                   |
| Key Words:   |                            |                   |
| Endogenous opiates   |                            |                   |
| Endotoxin shock  |                            |                   |
| Metabolic pathophysiology  |                            |                   |

|   |                    |                 |
|---|--------------------|-----------------|
| Accumulative MEDCASE  | Est Accumulative   | Periodic        |
| Cost:   | OMA Cost: \$19,413 | Review Results: |
| Objective: To determine the influence of stress released endogenous opiates on hormonal release by the endocrine pancreas (insulin, glucagon, pancreatic polypeptide and somatostatin) as a result of infection or endotoxin shock. |                    |                 |

Technical Approach: Plasma  $\beta$  endorphin ( $\beta$ -EP), methionine enkephalin (MET-ENK), immunoreactive insulin (IRI) and glucose responses were measured over a 6 hour period in fasted, anesthetized dogs divided into groups given either (1) an LD<sub>70</sub> dose of E. coli endotoxin, (2) endotoxin and glucose, (3) endotoxin, glucose and naloxone (infused continuously at a rate of 500  $\mu$ g/kg/hr), (4) glucose and naloxone, or (5) glucose alone.

Progress: Plasma  $\beta$ -EP response was rapid with a two fold increase within 5 minutes of endotoxin administration plateauing at 270 min at  $126 \pm 27$  pM/L ( $n = 11$ ).  $\beta$ -EP response in animals given glucose alone remained basal while  $\beta$ -EP in the naloxone animals were consistently higher than basal after 120 min ( $16 \pm 6$  vs  $38 \pm 14$  pM/L at 360 min). Plasma MET-ENK responses paralleled  $\beta$ -EP but lagged approximately 90 min. Naloxone alone did not induce an increase in MET-ENK over basal values. Plasma IRI in dogs given endotoxin and glucose was  $1935 \pm 1027$   $\mu$ U/ml at 360 min. Naloxone treated dogs given endotoxin and 360 min of  $198 \pm 58$   $\mu$ U/ml, although IRI did not suppress to values seen in dogs given only glucose ( $46 \pm 11$   $\mu$ U/ml). Interestingly in dogs given naloxone and glucose, IRI was stimulated to levels equivalent to the IRI values in endotoxin dogs treated with naloxone. In conclusion,

C-14-81 (continued)

naloxone clearly inhibits the marked IRI response suggesting a definite role of endogenous opiates in glucose induced hyperinsulinism in endotoxin shock. Additionally, naloxone itself appears to stimulate IRI release either directly or by blocking a tonic inhibitory mechanism.

# Detail Summary Sheet

Date: 4 Oct 83 Proj No: C-15-81 Status: Terminated

## TITLE:

Diabetogenicity of Venezuelan Equine Encephalomyelitis Virus.

|                                       |           |                            |
|---------------------------------------|-----------|----------------------------|
| Start Date                            | 11 Mar 81 | Est Comp Date:             |
| Principal Investigator                |           | Facility                   |
| James H. Anderson, Jr., M.D., LTC, MC |           | Brooke Army Medical Center |
| Dept/Sec                              |           | Associate Investigators:   |
| Department of Clinical Investigation  |           | Gerald A. Merrill, DAC     |
| Key Words:                            |           |                            |
| Diabetogenicity                       |           |                            |
| Venezuelan equine encephalomyelitis   |           |                            |

|   |                    |                 |
|---|--------------------|-----------------|
| Accumulative MEDCASE  | Est Accumulative   | Periodic        |
| Cost:   | OMA Cost: \$11,811 | Review Results: |
| Objective: To examine the hypothesis that Venezuelan equine encephalomyelitis (VEE) vaccine virus is diabetogenic in animals. |                    |                 |

Technical Approach: None.

Progress: A more comprehensive study will be undertaken under protocol C-40-83.

Since the two studies are so closely related, it was elected to terminate this study.

# Detail Summary Sheet

|  |                            |                 |         |         |         |
|--|----------------------------|-----------------|---------|---------|---------|
| Date:  | 6 Oct 83                   | Proj No:        | C-28-81 | Status: | Ongoing |
| TITLE:   |                            |                 |         |         |         |
| In vitro Synthesis of Immunoglobulins and Suppressor Cell Activity in Patients with Solid Tumors and Lymphomas on and off Therapy. |                            |                 |         |         |         |
| Start Date   | 1 Apr 81                   | Est Comp Date:  | Jun 84  |         |         |
| Principal Investigator   | Facility                   |                 |         |         |         |
| David G. Burleson, Ph.D., MAJ, MSC   | Brooke Army Medical Center |                 |         |         |         |
| Dept/Sec   | Associate Investigators:   |                 |         |         |         |
| Department of Clinical Investigation   | James Boyd, M.D., LTC, MC  |                 |         |         |         |
| Key Words:   | Karen Wolcott, DAC, GS-7   |                 |         |         |         |
| Suppressor cell activity   |                            |                 |         |         |         |
| Lymphoma   |                            |                 |         |         |         |
| Solid tumors   |                            |                 |         |         |         |
| Immunoglobulins  |                            |                 |         |         |         |
| Accumulative MEDCASE   | Est Accumulative           | Periodic        |         |         |         |
| Cost:  | OMA Cost: \$2,505          | Review Results: |         |         |         |

Objectives: To evaluate the in vitro synthesis of immunoglobulins in patients with different types of tumors.

To determine whether suppressor T-cell activity is increased in patients with lymphoma as compared with solid tumor patients.

To assess the effect of chemotherapy on immunoglobulin synthesis and suppressor cell activity in both groups of patients.

Technical Approach: 20 cc of blood are obtained from each patient by venipuncture. Peripheral blood lymphocytes are isolated by sedimentation on Ficoll-Hypaque. The cells are assayed for their proliferative responses to mitogens and their ability to synthesize immunoglobulins (Ig) by a reverse hemolytic plaque assay. Mixed lymphocyte cultures are also carried out to determine the cell's ability to suppress proliferation and antibody synthesis by normal lymphocytes.

The isolated lymphocytes will also be analyzed by the FACS using fluorescein labeled monoclonal antibody to detect surface markers. Cells will be analyzed for Leu 2a (suppressor) and Leu 3 (helper) antigens and surface Ig (Ig D, M, G). Cells cultured with PWM will be monitored for surface Ig in an attempt to detect shifts from one Ig class to another as an indicator of B cell stimulation. This may be a quicker and more sensitive assay of B cell activity than the plaque assay.

Progress: Forty-eight patients have been entered on the study. No progress was possible this year because of a lack of technical support. Every effort will be made to carry out proposed protocol during the upcoming year.

# Detail Summary Sheet

|   |   |                          |
|---|---|--------------------------|
| Date: 7 Oct 83  | Proj No: C-53-81                            | Status: Completed        |
| TITLE: The Use of Monoclonal Antibody to a Pseudomonas Ribosomal Protein Antigen for Passive Immunization Against P. aeruginosa.  |   |                          |
| Start Date 6 Aug 81   | Est Comp Date:                              |                          |
| Principal Investigator Michael M. Lieberman, Ph.D., CPT, MSC  | Facility Brooke Army Medical Center         |                          |
| Dept/Sec Department of Clinical Investigation   | Associate Investigators: Eleanor Ayala, DAC |                          |
| Key Words: Monoclonal antibody<br>Pseudomonas<br>Ribosomal protein antigen  |   |                          |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: \$3,928          | Periodic Review Results: |
| Objective: To determine whether monoclonal antibody to a Pseudomonas ribosomal protein antigen can protect mice by passive immunization against challenge with P. aeruginosa. |   |                          |

Technical Approach: BALB/C mice were immunized with the Pseudomonas ribosomal vaccine on outer membrane protein preparation. Spleens were excised and spleen cell suspensions prepared. Hybridomas were produced by fusion of a non-secreting BALB/C murine myeloma cell line with BALB/C immune spleen cells immunized either in vivo or in vitro with the Pseudomonas ribosomal vaccine or outer membrane protein (OMP) preparation.

Hybridoma clones produced were tested for antibody production to ribosomes, lipopolysaccharide (LPS) or OMP. Antibody positive hybridomas were subcultured and injected into the peritoneal cavity of mice. The ascitic fluid was collected from the mice and purified by ammonium sulfate precipitation. Monoclonal antibodies obtained were characterized for antigenic specificity and isotope and were tested for passive mouse protection.

Progress: Fusion of mouse myeloma cells with in vivo or in vitro immunized spleen cells yielded stable hybridomas which were grown in tissue culture and cloned by limiting dilution at least two times. Hybridomas producing antibodies of different specificities were found: 1) reactive with purified ribosomes but not with purified LPS, 2) reactive with purified LPS but not with ribosomes, and 3) reactive only with outer membranes. Isotyping results showed that most antibodies were of the  $\gamma_1$  or  $\gamma_{2b}$  heavy chain and  $\lambda$  light chain subclasses.

# Detail Summary Sheet

|   |                                       |                |                          |                            |         |
|---|---------------------------------------|----------------|--------------------------|----------------------------|---------|
| Date:   | 12 Oct 83                             | Proj No:       | C-16-82                  | Status:                    | Ongoing |
| TITLE:  |                                       |                |                          |                            |         |
| The Use of Biosynthetic Human Insulin in the Treatment of Insulin-Dependent Diabetes Mellitus in Patients Who Have Never Received Insulin |                                       |                |                          |                            |         |
| Start Date  | 20 Oct 81                             | Est Comp Date: | Indefinite               |                            |         |
| Principal Investigator  | James H. Anderson, Jr., M.D., LTC, MC |                | Facility                 | Brooke Army Medical Center |         |
| Dept/Sec  | Department of Clinical Investigation  |                | Associate Investigators: |                            |         |
| Key Words:  |                                       |                |                          |                            |         |
| Insulin-dependnet diabetes mellitus   |                                       |                |                          |                            |         |
| Biosynthetic human insulin  |                                       |                |                          |                            |         |

|   |                  |                 |
|---|------------------|-----------------|
| Accumulative MEDCASE  | Est Accumulative | Periodic        |
| Cost:   | OMA Cost:        | Review Results: |
| Objectives: To evaluate the efficacy and safety of Biosynthetic Human Insulin (BHI) in the treatment of insulin-dependent diabetes. |                  |                 |

To detect, if present, immunologic evidence of E. coli proteins in patients who have received BHI.

Technical Approach: Newly diagnosed insulin-dependent diabetics are begun on biosynthetic human insulin using only regular insulin delivered by means of a continuous subcutaneous insulin infusion pump. This is a cooperative study with the Eli Lilly Company.

Progress: Two patients have been entered on the study. Both patients are doing well with no complications from the insulin or pump. No adverse effects have been detected.

# Detail Summary Sheet

|   |   |                          |                            |         |            |
|---|---|--------------------------|----------------------------|---------|------------|
| Date:   | 7 Oct 83  | Proj No:                 | C-43-82                    | Status: | Terminated |
| TITLE:  |   |                          |                            |         |            |
| Immunogenicity of <u>Pseudomonas aeruginosa</u> Ribosomal Vaccines in a Cystic Fibrosis Animal Model.   |   |                          |                            |         |            |
| Start Date  | Jul 82  | Est Comp Date:           |                            |         |            |
| Principal Investigator  | Michael M. Lieberman, Ph.D., CPT, MSC                                 |                          | Facility                   |         |            |
| Dept/Sec  | Department of Clinical Investigation                                  |                          | Brooke Army Medical Center |         |            |
| Key Words:  | <u>Pseudomonas aeruginosa</u><br>Ribosomal vaccine<br>Cystic fibrosis |                          | Associate Investigators:   |         |            |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:  | Periodic Review Results: |                            |         |            |
| Objective: To evaluate the efficacy of a vaccine prepared from the ribosomal fraction of <u>Pseudomonas aeruginosa</u> in an animal mode for cystic fibrosis. |   |                          |                            |         |            |

Technical Approach: None.

Progress: This protocol was not initiated due to lack of personnel support. As stipulated in the protocol, one full-time dedicated technician was required for accomplishment of this work. This requirement was not fulfilled.



# Detail Summary Sheet

Date: 7 Oct 83 Proj No: C-64-82 Status: Completed

## TITLE:

A Study of the Efficacy of a Pseudomonas aeruginosa Ribosomal Vaccine in the Burned Rat Model.

Start Date 24 Sep 82 Est Comp Date:

Principal Investigator Facility

Michael M. Lieberman, Ph.D., CPT, MSC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Clinical Investigation

Key Words:

Pseudomonas aeruginosa

Ribosomal vaccine

Accumulative MEDCASE Est Accumulative Periodic

Cost: OMA Cost: \$2,755 Review Results:

Objectives: To assess the efficacy of a ribosomal vaccine prepared from Pseudomonas aeruginosa in the burned rat (20% total body surface) animal model.

To assess the ability of antiserum raised against the Pseudomonas ribosomal vaccine to protect burned rats by passive immunization against challenge with P. aeruginosa.

Technical Approach: Ribosomal vaccines were be prepared from specific strains of P. aeruginosa. The burned rat model employed consisted of a ten-second scald (using boiling water) administered to anesthetized rats with 20% of their total body surface exposed. This resulted in a full thickness burn on the exposed area with no lesions on the non-exposed area. The prepared vaccines were used for two purposes: (1) to vaccinate groups of rats either before or after burning; (2) to vaccinate groups of rabbits for the production of specific antisera to the vaccines. The antisera was then administered to burned rats either as prophylaxis ("passive protection") or specific therapy for established infections with P. aeruginosa.

Progress: When administered prior to burning. the vaccines provided 100% protection. When administered post burning, the vaccine from one strain also provided 100% protection when the same time interval between vaccination and infection was three days. When this time interval was reduced to one or two days, approximately 50% protection was obtained with the same vaccine. The vaccine from a second strain tested provided about 50% protection with a three day time interval. In addition, passive immunization using antiserum to a ribosomal vaccine was also demonstrated to be effective in protectin burned and infected rats, especially when multiple doses of antiserum were used. In this case, 80% protection was obtained (with no protection observed using multiple doses of normal serum). Finally, in a comparison of ribosomal and

C-64-82 (continued)

lipopolysaccharide (LPS) vaccines, LPS appeared to require a slightly shorter interval between vaccination (post burning) and challenge for effective protection. A one day interval was sufficient to yield 80% protection. Antiserum to LPS also afforded passive immunity, but slightly less than antiserum to ribosomes, 50% protection compared to 80% protection, respectively, under the same conditions.

# Detail Summary Sheet

Date: 7 Oct 83 Proj No: C-40-83 Status: Ongoing

## TITLE:

Viral Infection and Diabetic Disease in Laboratory Animals.

|                        |   |                          |                                       |
|------------------------|---|--------------------------|---------------------------------------|
| Start Date             | 6 May 83  | Est Comp Date:           | May 85                                |
| Principal Investigator | Carl E. Pedersen, Jr., LTC, MSC                     | Facility                 | Brooke Army Medical Center            |
| Dept/Sec               | Department of Clinical Investigation                | Associate Investigators: | James H. Anderson, Jr., M.D., LTC, MC |
| Key Words:             | Venezuelan equine Encephalomyelitis<br>pancreopathy |                          |                                       |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine whether VEE virus subtypes localize and replicate in pancreatic tissue, as well as the degree of virus induced pancreopathy, the proposed experiments will determine whether attenuated VEE viruses do indeed replicate the pancreas and to what degree; and whether focal pancreatic lesions are indeed virus-induced or the consequence of other events.

Technical Approach: Acute experimentation studies have not begun.

Progress: Progress has consisted of establishing priorities for the establishment of a containment environment within which to study these agents. A Class II hood has been received, and plans are being formulated for the preparation of a suite to handle Class II (CDC) viruses.

# Detail Summary Sheet

|   |                  |                            |         |         |         |
|---|------------------|----------------------------|---------|---------|---------|
| Date:   | 6 Oct 83         | Proj No:                   | C-41-83 | Status: | Ongoing |
| TITLE:  |                  |                            |         |         |         |
| Rheumatoid Synovial Dendritic Cell - Its Possible Origin and Regulation of Collagenase Production.                  |                  |                            |         |         |         |
| Start Date  | 7 Jun 83         | Est Comp Date:             | Jun 84  |         |         |
| Principal Investigator (vice Patel)   |                  | Facility                   |         |         |         |
| Debra J. Krikorian, Ph.D., CPT, MSC   |                  | Brooke Army Medical Center |         |         |         |
| Dept/Sec  |                  | Associate Investigators:   |         |         |         |
| Department of Clinical Investigation  |                  |                            |         |         |         |
| Key Words:  |                  |                            |         |         |         |
| Rheumatoid dendritic cell   |                  |                            |         |         |         |
| Collagenase assay   |                  |                            |         |         |         |
| Accumulative MEDCASE  | Est Accumulative | Periodic                   |         |         |         |
| Cost:   | OMA Cost:        | Review Results:            |         |         |         |
| Objective: To determine the production of collagenase by the rheumatoid dendritic cell utilizing collagenase assay. |                  |                            |         |         |         |

Technical Approach: Rheumatoid dendritic cells will be cultured and collagenase production will be assayed. Conditioned medium will be removed from the cells and tested for the presence of collagenase. This will be accomplished by observing the amount of radiolabeled collagen present after timed exposure to the conditioned.

Progress: Since taking over as principal investigator of this protocol, two samples have been received and processed in an attempt to culture and maintain dendritic cells. Only one of these procedures was successful but only ~ 2% of the sample was the proper cell type and these few cells were only maintained for one week. The assay has not been attempted.

# Detail Summary Sheet

Date: 6 Oct 83 Proj No: C-45-83 Status: Ongoing

## TITLE:

Development of a Chemiluminescent Enzyme Linked Immunoassay (CELIA) System for Detection of Antigens of Medical Importance in Serum and Tissue Fluids.

|                        |                                      |                          |  |
|------------------------|--------------------------------------|--------------------------|--|
| Start Date             | 17 May 83                            | Est Comp Date:           | May 86                                   |
| Principal Investigator | Gerald A. Merrill, DAC               | Facility                 | Brooke Army Medical Center               |
| Dept/Sec               | Department of Clinical Investigation | Associate Investigators: | Robert C. Allen, M.D., Ph.D.,<br>MAJ, MC |
| Key Words:             | CELIA                                |                          |  |

|                            |                                    |                          |
|----------------------------|------------------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: \$2,956 | Periodic Review Results: |
|----------------------------|------------------------------------|--------------------------|

Objectives: To develop an enzyme-linked antibody system for antigen-specific detection of fungi, bacteria, viral agents, hormones, and immune complexes.

Animal studies will be designed to provide a source of halcperoxidase for characterization of enzyme activity.

Technical Approach: Whole blood (obtained from the Clinical Lab at Beach Pavilion after completion of laboratory tests) and expired blood packs obtained from the Blood Bank were processed as a source of human myeloperoxidase. Processing involved collection of buffy coats and separation of erythrocytes by repetitive hypotonic lysings. The leukocytes so obtained were then extracted for myeloperoxidase which was purified by use of FPLC (fast protein liquid chromatography). Fresh nonhuman granulocytes, to be used to study microbicidal activity of various enzymes and to be a source of nonhuman myeloperoxidase involves inducing a sterile inflammatory response in target animals and recovery of cells in large quantities by peritoneal lavage.

Progress: A substantial pool of human leukocytes has been obtained. Processing of these leukocytes has provided a limited quantity of purified myeloperoxidase for analysis. Purification of this enzyme by FPLC has greatly reduced the purification procedure resulting in an enzyme of theoretical purity in a much shorter time. The limitation to obtaining large quantities of myeloperoxidase for enzyme kinetics is now the time required to isolate the buffy coats. Procedures to reduce this portion of the procedure are being examined. The use of peritoneal lavage in nonhumans has not been successful, primarily due to the inability to repeatedly lavage the same animal. A modified procedure utilizing a device designed for peritoneal dialysis is to be evaluated, and leukophoresis of large animals is also being considered.

Study of the microbicidal enzymes of granulocytes has thus far been confined to chicken granulocytes (PMNLs). A demonstration of an oxidative response (as measured by chemiluminescence) in these cells has provided evidence for an oxygen dependent myeloperoxidase independent microbicidal activity which may be analogous to the initial step of microbicidal activity in human granulocytes. Biochemical parameters ( $V_{max}$  and  $K_m$ ) have been obtained for each of the chemiluminogenic probes utilized. Results confirm that chicken PMNLs do not have a peroxidase activity which is involved in cellular microbicidal activity. These results however do indicate an oxidase is involved with the oxidative response to phagocytosis. Further characterization of the enzyme responsible for the chemiluminescence by use of enzyme inhibitors is in progress.

# Detail Summary Sheet

Date: 7 Oct 83 Proj No: C-72-83 Status: Ongoing

## TITLE:

An Investigation into Biotyping of Staphylococcus epidermidis Sensu Stricto and Correlation of Biotype with Virulence and Human Disease.

Start Date 30 Sep 83

Est Comp Date: Dec 84

Principal Investigator

Facility

Bruce A. Gunn, Ph.D., MAJ, MSC

Brooke Army Medical Center

Dept/Sec

Associate Investigators:

Department of Clinical Investigation

William Nauscheutz, M.S., CPT, MSC

Key Words:

Staphylococcus epidermidis

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost: \$640

Review Results:

Objectives: Clinical strains of S. epidermidis will be tested for presence of selected morphologic and physiologic characters.

Phenotype profiles will be used to sort strains of S. epidermidis into biotypes.

Biotypes will be correlated with: 1) significance in human disease; 2) resistance to antibiotics; 3) predilection for a certain body site; 4) possession of virulence factors; and 5) virulence, as measured by growth rate, delta toxin, tissue culture, and mouse virulence assays.

Technical Approach: Strains of S. epidermidis sensu stricto cultured from blood, urine, wounds, and fluids will be assessed as to their significance in human disease.

Ten or more organisms from each of nine category types will be selected and identified using a commercially available identification kit. The first ten strains from each category identified as S. epidermidis sensu stricto will be studied. Strains identified as one of the other eight recognized coagulase-negative species will be stored on agar slant media for use later. Thus, 90 strains of S. epidermidis will be selected for study. Significance in human disease will be correlated with resistance to antibiotics, site of infection, production of virulence factors, and biotype.

Progress: None; this is a new study.

# Detail Summary Sheet

Date: 7 Oct 83 Proj No: C-73-83 Status: Ongoing

## TITLE:

The Effect of Lysine on Herpes Simplex Virus (HSV) Infection.

|  |  |
|--|--|
| Start Date 30 Sep 83                                 | Est Comp Date: Oct 85                  |
| Principal Investigator<br>Eleanor Ayala, MT, DAC     | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department of Clinical Investigation     | Associate Investigators:               |
| Key Words:<br>Herpes simplex virus (HSV)<br>L-lysine |  |
| Accumulative MEDCASE<br>Cost:                        | Est Accumulative<br>OMA Cost: \$554    |
|  | Periodic<br>Review Results:            |

Objective: To evaluate the in vitro effect of L-lysine on HSV infected cells and the in vivo effect of topical applications of L-lysine in treatment of HSV skin infections in laboratory animals.

Technical Approach: Studies will be performed to determine the maximum concentration of L-lysine non-toxic to cultured cells (i.e. mouse dorsal root ganglia (MDRG), guinea pig dorsal roog ganglion (GPDRG), human cell lines, and primary rabbit kidney cells).

Plaque titration of HSV-1 in medium plus lysine at the maximum concentration nontoxic to cultured cells will be performed. All cultures will be examined for cytopathic effect (CPE).

Cells will be examined by light and electron microscopy for morphological changes in vitro.

In the in vivo studies, efforts will be directed toward the study of the effect of topical application of L-lysine on cutaneous HSV-1 infections in the guinea pig model.

Progress: None; this is a new study.



# Detail Summary Sheet

|  |                            |                                   |
|--|----------------------------|-----------------------------------|
| Date: 1 Oct 83   | Proj No: C-62-81           | Status: Ongoing                   |
| TITLE: Effect of Supplemental Nasal Oxygen on the PO <sub>2</sub> of Patients Undergoing Outpatient Oral Surgery |                            |                                   |
| Start Date 23 Sep 81   | Est Comp Date: Feb 84      |                                   |
| Principal Investigator   | Facility                   |                                   |
| Richard A. Kraut, D.D., LTC, DC  | Brooke Army Medical Center |                                   |
| Dept/Sec   | Associate Investigators:   |                                   |
| Department of Dentistry/Oral Surgery   |                            |                                   |
| Key Words:   |                            |                                   |
| Nasal oxygen   |                            |                                   |
| PO <sub>2</sub>  |                            |                                   |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: Continue |

Objective: To determine the changes from baseline PO<sub>2</sub> in patients undergoing outpatient oral surgery with supplemental nasal oxygen utilizing local anesthesia or local anesthesia plus intravenous Valium and Sublimaze.

Technical Approach: The effect of two different methods of delivering nasal oxygen is being determined on patients undergoing outpatient oral surgery. This study consists of four study groups, two of which receive supplemental oxygen via nasal prongs, two of which receive supplemental oxygen via nasal mask. To date, the 20 patients in each of the two study groups receiving sedation have been completed with no adverse effect. There is a lack of patients having outpatient oral surgery without sedation which has hampered completion of this study.

Progress: The two groups who received intravenous sedation along with the supplemental oxygen have been completed and arrangements have been made to transport the monitoring equipment to the Budge Dental Clinic to obtain patients having exodontia accomplished under local anesthesia.

# Detail Summary Sheet

|   |          |                            |   |         |           |
|---|----------|----------------------------|---|---------|-----------|
| Date:   | 3 Oct 83 | Proj No:                   | C-5-82  | Status: | Completed |
| TITLE:<br>Evaluation of EKG Changes in Dentists Treating Awake Patients                                       |          |                            |   |         |           |
| Start Date 21 Oct 81  |          |                            | Est Comp Date:  |         |           |
| Principal Investigator<br>L. P. Bilodeau, D.D.S., MAJ, DC   |          |                            | Facility<br>Brooke Army Medical Center                        |         |           |
| Dept/Sec<br>Department of Dentistry/Oral Surgery  |          |                            | Associate Investigators:<br>Richard A. Kraut, D.D.S., LTC, DC |         |           |
| Key Words:<br>Holter monitors<br>EKG changes  |          |                            |   |         |           |
| Accumulative MEDCASE Cost:  |          | Est Accumulative OMA Cost: | Periodic Review Results:                                      |         |           |
| Objective: To measure changes in cardiac rate and associated arrhythmias in dentists while treating patients. |          |                            |   |         |           |

Technical Approach: Twenty-eight male dentists were evaluated. Patients with known cardiac pathology or those taking cardiovascular drugs were excluded with the exception of individuals with mild hypertension.

Each subject was evaluated by history and physical examination, with attention directed to coronary risk factors, the taking of prescription medicines and level of participation in athletic activities. A routine 12 lead ECG as well as posterior-anterior and lateral chest x-ray were obtained. A two lead 24-hour Holter monitor recording was obtained during a routine work day. Each individual was required to keep a diary of his activities and symptoms. Any symptom referred to in the diary was evaluated; particularly, chest pain, fainting, shortness of breath, and nausea. The Holter recordings were examined for variations in PR interval, supraventricular and ventricular arrhythmias, S-T segment changes and correlated with symptoms and activities.

Progress: The volunteers ranged in age from 26 to 55 years with a mean age of 37. Only one of the participants showed any sign of stress induced arrhythmias; however, this occurred after a patient fainted. The remainder of the subjects were indistinguishable from normal reported populations.

# Detail Summary Sheet

Date: 1 Oct 83 Proj No: C-52-82 Status: Completed

## TITLE:

A Comparison of Intravenous and Laryngotracheal Lidocaine Before Endotracheal Intubation

Start Date 13 Aug 82 Est Comp Date:

Principal Investigator Facility

Richard A. Kraut, D.D.S., LTC, DC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Dentistry/Oral Surgery

## Key Words:

Laryngotracheal lidocaine

Intravenous lidocaine

Endotracheal intubation

Accumulative MEDCASE Est Accumulative Periodic

Cost: OMA Cost: Review Results:

Objectives: To describe the effect of intravenous lidocaine compared to laryngotracheal lidocaine in patients having wisdom teeth removed under general anesthesia.

To determine if there is a preferred route for administration of lidocaine before endotracheal intubation.

Technical Approach: Fifty consecutive patients who requested outpatient general anesthesia in association with removal of their impacted wisdom teeth constituted the study group. Patients were alternately selected for intravenous or laryngotracheal lidocaine. Monitors consisting of an electrocardiograph, pneumotachograph, precordial stethoscope and Dinamap Model 950 with an in-line trend recorder were applied and baseline recordings obtained. Prior to induction of anesthesia, a 3 mg defasciculating dose of curare, a .4 mg dose of atropine, and an 8 mg dose of dexamethasone sodium phosphate were administered intravenously. Oxygenation for 60 seconds via full face mask was followed by induction of anesthesia with 100 mgs of methohexital sodium. Once control of the airway was established 100 mgs of succinylcholine was administered. Forty-five seconds after induction of anesthesia, 25 of the patients received 4 ml of 4% lidocaine to the laryngotracheal area under direct vision with a #3 Macintosh laryngoscope, through a standard LTA<sup>R</sup> II Kit. The alternate 25 patients received 1.5 mg/kg of lidocaine intravenously 45 seconds after induction of anesthesia. Ninety seconds after induction of anesthesia, both study groups underwent laryngoscopy with a #3 Macintosh blade, and endotracheal intubation was accomplished within 15 seconds. The tube placement was verified via auscultation of the lungs and the patient was anesthetized with 70% nitrous oxide, 30% oxygen, and 1.5% enflurane, delivered through an enflurane vaporizer and a Bain anesthetic circuit with a fresh gas flow of 100 cc per kilogram per minute. The patients were maintained on 70% nitrous oxide and 30% oxygen throughout the procedure with the percentage of enflurane continually reduced from 1.5% during the surgery to as low a level as possible consistent with the patient's vital signs and maintenance of a favorable operating environment. Blood pressure was ascertained and recorded automatically at one minute intervals, via the in-line trend recorder.

Progress: There was no difference between the groups with respect to age or gender. The group treated with intravenous lidocaine consisted of 17 females with a mean age of 20.5 years and eight males with a mean age of 20.1 years. The group treated with laryngotracheal lidocaine consisted of 18 females with a mean age of 20.7 years and seven males with a mean age of 22.6 years. The group treated with intravenous lidocaine demonstrated a 31.68 mm of Hg increase in mean arterial pressure as a result of laryngoscopy and endotracheal intubation. The group with laryngotracheal lidocaine demonstrated a 29.56 mm of Hg increase in mean arterial pressure as a result of laryngoscopy and endotracheal intubation. Based on two-way analysis of variance, no significant interaction was found between the two groups. There is a significant transient change with time in both groups at the  $P < .001$  level. Scheffé tests indicated that the two groups were statistically different at the  $P < .01$  level at all times except at minutes one and three; at these times the groups were not statistically different. The group treated with laryngotracheal lidocaine returned to baseline MAP between 9 and 10 minutes after induction of anesthesia. The group treated with intravenous lidocaine returned to baseline MAP between 13 and 14 minutes after induction. Standard deviation and standard errors were comparable within the two groups at all 15 time intervals.

Conclusions: Based on the significantly larger increase in MAP in the intravenous lidocaine group during the three through 13 minute anesthetic period, it appears that laryngotracheal lidocaine is the preferred route to minimize the duration of hypertension associated with endotracheal intubation in patients undergoing ambulatory surgical removal of wisdom teeth.

# Detail Summary Sheet

Date: 1 Oct 83 Proj No: C-54-82 Status: Ongoing

## TITLE:

Evaluation of  $PO_2$  Changes Associated with Intravenous Sedation for Outpatient Oral Surgery

Start Date 13 Aug 82

Est Comp Date: Mar 84

Principal Investigator

Facility

Richard A. Kraut, D.D.S., LTC, DC

Brooke Army Medical Center

Dept/Sec

Associate Investigators:

Department of Dentistry/Oral Surgery

Key Words:

Transcutaneous oxygen ( $PtcO_2$ )

Intravenous sedation

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Periodic  
Review Results: Continue

Objectives: To determine the change from baseline  $PtcO_2$  in patients undergoing outpatient oral surgery utilizing local anesthesia, intravenous diazepam, fentanyl, and methohexital.

To determine the effect of 6 liters/min  $O_2$  on the  $PtcO_2$  of patients undergoing outpatient oral surgery utilizing local anesthesia and intravenous diazepam, fentanyl, and methohexital.

Technical Approach: This project was delayed due to the transcutaneous oxygen monitor having been stolen from the Oral Surgery Clinic. The monitor has now been replaced and the project will start in the immediate future.

Progress: Study deferred due to transcutaneous oxygen monitor having been stolen. Monitor has been replaced and study will start in the near future.

# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-59-82 Status: Terminated  
 TITLE:

The Relationships of Soft and Hard Tissue Changes in Combined Maxillary and Mandibular Surgical Procedure.

|                                      |                            |
|--------------------------------------|----------------------------|
| Start Date 8 Sep 82                  | Est Comp Date:             |
| Principal Investigator               | Facility                   |
| George D. Suchko, D.D.S., MAJ, DC    | Brooke Army Medical Center |
| Dept/Sec                             | Associate Investigators:   |
| Department of Dentistry/Oral Surgery |                            |
| Key Words:                           |                            |
| Maxillary repositioning              |                            |
| Mandibular repositioning             |                            |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To assess the effects of combined maxillary and mandibular surgery on soft and hard tissues and to compare our findings with prior studies done which evaluated changes noted after single jaw surgical procedures.

Technical Approach:

Progress: This study was terminated because of an inability to obtain an adequate number of patients in the required time frame.

# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-65-82 Status: Ongoing

## TITLE:

Electrocardiographic Changes During Outpatient Oral Surgery.

|   |  |
|---|--|
| Start Date 24 Sep 82  | Est Comp Date: Jun 84                  |
| Principal Investigator<br>Richard A. Kraut, D.D.S., LTC, DC | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department of Dentistry/Oral Surgery            | Associate Investigators:               |
| Key Words:<br>Electrocardiographic changes<br>Dysrhythmias  |  |

|                               |                               |                                      |
|-------------------------------|-------------------------------|--------------------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: Continue |
|-------------------------------|-------------------------------|--------------------------------------|

Objective: To determine the type and frequency of dysrhythmias that occur during outpatient oral surgery.

Technical Approach: Patients undergoing outpatient oral surgery are connected to an ECG machine which is equipped with a computerized circuit to enable detection of alteration of rhythm during surgery.

Progress: Due to changes in personnel within the Oral and Maxillofacial Surgery Service, this project has been slower than anticipated. However, there have been no adverse effects in the 25 patients monitored.

# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-25-83 Status: Ongoing

## TITLE:

Determination of Transcutaneous Oxygen (PtcO<sub>2</sub>) During the Perioperative Period of Patients Undergoing Orthognathic Surgery

Start Date 16 Mar 83 Est Comp Date: Jun 84

Principal Investigator

Facility

Richard A. Kraut, D.D.S., LTC, MC

Brooke Army Medical Center

Dept/Sec

Associate Investigators:

Department of Dentistry/Oral Surgery

Key Words:

Transcutaneous oxygen

Orthognathic surgery

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost:

Review Results:

Objectives: To determine the baseline PtcO<sub>2</sub> of each patient studied.

To determine the PtcO<sub>2</sub> of patients who have just undergone orthognathic surgery and who are still intubated.

To determine the PtcO<sub>2</sub> when patients are extubated following orthognathic surgery.

To determine the PtcO<sub>2</sub> in patients 48 hours after orthognathic surgery.

Technical Approach: This study was delayed due to the loss of the transcutaneous oxygen monitor which has now been replaced. there are no patients currently completed in this study.

Progress: This study is anticipated to start on or about 1 Nov 83. It is anticipated that it will run approximately six months to completion.



# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-59-83 Status: Ongoing

## TITLE:

A Comparison of the Effects of Ethrane and Forane on  $PO_2$ ,  $PCO_2$ , Blood Pressure and Pulse When Used for Outpatient Oral Surgery

Start Date 10 Aug 83

Est Comp Date:

Principal Investigator

Facility

Glenn J. Reside, D.D.S., MAJ, DC

Brooke Army Medical Center

Dept/Sec

Associate Investigators:

Department of Dentistry/Oral Surgery

## Key Words:

Ethrane

Forane

$PO_2$

$PCO_2$

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost:

Review Results:

Objective: To compare the changes from baseline  $PO_2$ ,  $PCO_2$ , blood pressure and pulse in patients undergoing outpatient general anesthesia with either Ethrane or Forane.

Technical Approach: Project has not been started.

Progress: None at this time.

# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-68-83 Status: Ongoing

## TITLE:

Evaluation of PO<sub>2</sub> Changes During Surgical Removal of Wisdom Teeth Utilizing Enflurane Anesthesia

Start Date 9 Sep 83

Est Comp Date: Feb 84

Principal Investigator

Facility

Richard A. Kraut, D.D.S., LTC, DC

Brooke Army Medical Center

Dept/Sec

Associate Investigators:

Department of Dentistry/Oral Surgery

David Glendening, M.D., LTC, MC

Key Words:

Bruce Bush, M.D., CPT, MC

Enflurane anesthesia

Herman Blanton, M.D., CPT, MC

PO<sub>2</sub>

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost:

Review Results:

Objectives: To determine if the two previously reported patient groups can be predicted based on preoperative pulmonary function testing.

To determine if the previously reported transcutaneous PO<sub>2</sub> values are truly reflective of the patient's PO<sub>2</sub> or if some patients enter a physiologic state which precludes meaningful transcutaneous oxygen monitoring during enflurane general anesthesia.

Technical Approach: Study has not started.

Progress: This is a new study.

# Detail Summary Sheet

|  |                            |                                   |         |         |         |
|--|----------------------------|-----------------------------------|---------|---------|---------|
| Date:  | 2 Nov 83                   | Proj No:                          | C-76-83 | Status: | Ongoing |
| TITLE: Evaluation of Changes in Transcutaneous Oxygen and Transcutaneous Carbon Dioxide in Patients with Chronic Obstructive Pulmonary Disease While Undergoing Outpatient Oral Surgery with Intravenous Sedation and Local Anesthesia |                            |                                   |         |         |         |
| Start Date   | 30 Sep 83                  | Est Comp Date:                    | Feb 84  |         |         |
| Principal Investigator   |                            | Facility                          |         |         |         |
| George D. Suchko, D.D., MAJ DC   |                            | Brooke Army Medical Center        |         |         |         |
| Dept/Sec   |                            | Associate Investigators:          |         |         |         |
| Department of Dentistry/Oral Surgery   |                            | Richard A. Kraut, D.D.S., COL, DC |         |         |         |
| Key words:   |                            |                                   |         |         |         |
| Transcutaneous oxygen  |                            |                                   |         |         |         |
| Transcutaneous carbon dioxide  |                            |                                   |         |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results:          |         |         |         |

Objectives: To determine the changes of baseline  $PtcO_2$  and  $PtcCO_2$  in patients with chronic obstructive pulmonary disease while undergoing outpatient oral surgical procedures under intravenous sedation and local anesthesia.

To evaluate the effects of flow  $O_2$  (1-2 liters) administered by nasal mask on baseline  $PtcO_2/PtcCO_2$ .

To evaluate the effects of sedation with intravenous diazepam (titrated in doses not to exceed 10 mg) on respiratory depression.

Technical Approach: Patients will be randomized to either Group A or Group B. Group A will undergo treatment as follows: 1) application of the oxygen and carbon dioxide monitor electrodes to the skin; 2) intravenous line with sugar water drip; 3) low flow oxygen via nasal mask; and 4) extraction(s) as needed done with intravenous sedation and local anesthesia. Group B patients will receive identical treatment with the exception that low flow oxygen via nasal mask will not be given.

Progress: This is a new study.

# Detail Summary Sheet

|  |  |                 |  |         |            |
|--|--|-----------------|--|---------|------------|
| Date:  | 7 Oct 83   | Proj No:        | C-32-82  | Status: | Terminated |
| TITLE:   |  |                 |  |         |            |
| Comparison of Speed and Complication Rate of Nasotracheal or Endotracheal Intubation by Standard Methods vs Fiber Optic Assisted Intubation. |  |                 |  |         |            |
| Start Date   | 18 May 82  | Est Comp Date:  |  |         |            |
| Principal Investigator   | Daniel J. Boyle II, M.D., CPT, MC                  |                 | Facility   |         |            |
| Dept/Sec   | Department of Emergency Medicine                   |                 | Brooke Army Medical Center   |         |            |
| Key Words:   | Nasotracheal intubation<br>Endotracheal intubation |                 | Associate Investigators:<br>William H. Dice, M.D., MAJ, MC<br>Victor L. Burgos, M.D., LTC, MC<br>Donald J. Gordon, M.D., LTC, MC |         |            |
| Accumulative MEDCASE   | Est Accumulative                                   | Periodic        |  |         |            |
| Cost:  | OMA Cost:  | Review Results: |  |         |            |
| Objective: To determine the quickest and safest method of rapid intubation in the Emergency Room.  |  |                 |  |         |            |

Technical Approach: None.

Progress: Study terminated. The method for conducting the study did not work, in that the skills to operate the equipment delayed treatment and therefore the residents abandoned the procedure.

# Detail Summary Sheet

Date: 12 Oct 83 Proj No: C-60-82 Status: Ongoing  
 TITLE:

The Effects of Pneumatic Trousers on Cardiovascular Hemodynamics

|   |   |
|---|---|
| Start Date 8 Sep 82   | Est Comp Date: Apr 84   |
| Principal Investigator<br>William H. Bickell, M.D., CPT, MC | Facility<br>Brooke Army Medical Center  |
| Dept/Sec<br>Department of Emergency Medicine/Medicine       | Associate Investigators:<br>Michael R. Gerr, M.D., MAJ, MC<br>William E. Craig, M.D., MAJ, MC<br>Joseph P. Murgo, M.D., COL, MC |
| Key Words:<br>Pneumatic trousers                            |   |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: To study the effects of external counterpressure on the cardiovascular system through invasive monitoring.

Technical Approach: Five normovolemic human volunteers previously selected for cardiac catheterization were involved in the study. Right and left heart catheterization with multisensor catheters was performed. External counter pressure with Jobst gladiator MAST was sequentially applied up to a maximum of 100 mm Hg with a total inflation time of 10 minutes. The MAST was rapidly deflated with serial measurements of the following parameters: Mean right atrial pressure (RAM), mean pulmonary artery pressure (PAM), left ventricular and diastolic pressure (LVEDP), mean arterial pressure (MAP).

Progress: Comparison of the pre and post deflation hemodynamics resulted in the following observations: A significant decrease in MAP of 37 mm Hg ( $P < .01$ ), in conjunction with a simultaneous significant decrease in right and left heart filling pressures; i.e., decrease in RAM, PAM, LVEDP of 81%, 58%, 81% respectively ( $P < .01$ ). Analysis of simultaneous right and left pressures using multisensor catheters suggest that the hypotensive response to rapid MAST deflation is secondary to a simultaneous decrease in both preload and afterload.

# Detail Summary Sheet

Date: 7 Oct 83 Proj No: C-61-82 Status: Completed

## TITLE:

Ionizing Radiation Exposure of Emergency Room Personnel.

|                                  |                            |  |  |
|----------------------------------|----------------------------|--|--|
| Start Date                       | 8 Sep 83                   | Est Comp Date:                         |  |
| Principal Investigator           |                            | Facility                               |  |
| Robert L. Kinsman, M.D., CPT, MC |                            | Brooke Army Medical Center             |  |
| Dept/Sec                         |                            | Associate Investigators:               |  |
| Department of Emergency Medicine |                            | Robert J. Matthews, Ph.D., CPT, MSC    |  |
| Key Words:                       |                            | William H. Dice, M.D., MAJ, MC         |  |
| Radiation exposure               |                            | Robert N. Cherry, Jr., Ph.D., CPT, MSC |  |
| Accumulative MEDCASE Cost:       | Est Accumulative OMA Cost: | Periodic Review Results:               |  |

Objective: To quantitate ionizing radiation exposure of medical personnel assigned to the Brooke Army Medical Center Emergency Room and to determine the need, if any, for routine personnel monitoring in accordance with AR 40-14.

Technical Approach: Exposure to ionizing radiation in the Emergency Department was measured in 39 physicians, nurses, and aides over one to two month periods. Participants wore lithium fluoride thermoluminescent dosimeters (TLD's) on the anterior chest. Prior to assigning the TLD's, each dosimeter was calibrated after two heat treatments using known x-ray energies. The TLD's were protected from random irradiation and soiling by sealing them in a plastic-opaque-paper package. All measurements were made using a Harshaw Model 2000 A thermoluminescence detector and a Harshaw Model 2000 B automatic integrating picometer. Participants did not alter their normal activities during the study period.

Progress: The average exposure for the study period was five millirads over a one month period. The range of exposures was from 0 to 10.5 millirads per month.

Although Emergency Department personnel may perceive that an excessive exposure to radiation exists, this study does not reflect a significant exposure to the personnel involved. This suggests that routine radiation monitoring of personnel in the Emergency Department is not necessary.

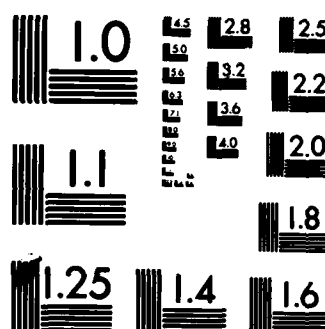
ANNUAL RESEARCH PROGRESS REPORT FOR FISCAL YEAR 1983  
(U) BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TX  
J H ANDERSON 01 OCT 83

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ANNUAL RESEARCH PROGRESS REPORT FOR FISCAL YEAR 1983  
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J H ANDERSON 01 OCT 83

A 10x10 grid of squares, with the top-left square missing, representing a 10x10 grid with a 1x1 hole.



MICROCOPY RESOLUTION TEST CHART  
NATIONAL BUREAU OF STANDARDS-1963-A



# Detail Summary Sheet

Date: 12 Oct 83 Proj No: C-8-83 Status: Ongoing

## TITLE:

The Effect of Using Isopropyl Alcohol for Venipuncture Skin Preparation on Determining Blood Alcohol Levels

|                        |                                  |                          |   |
|------------------------|----------------------------------|--------------------------|---|
| Start Date             | 10 Nov 82                        | Est Comp Date:           | May 84  |
| Principal Investigator | Matthew M. Rice, M.D., MAJ, MC   | Facility                 | Brooke Army Medical Center                                      |
| Dept/Sec               | Department of Emergency Medicine | Associate Investigators: | William H. Dice, M.D., MAJ, MC<br>Susanne Smith, R.N., 1LT, ANC |
| Key Words:             | Blood alcohol<br>Venipuncture    |                          |   |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objective: To study the effect of using an isopropyl alcohol skin preparation on legal blood alcohol specimens obtained by venipuncture. |                            |                          |

Technical Approach: One hundred healthy male and female volunteers will be randomly divided into two groups. At time zero each volunteer will consume two 12 ounce glasses of beer. Thirty minutes after ingestion two simultaneous 7 cc tubes of venous blood will be obtained, one from each antecubital fossae.

Sampling sites will be prepared using either isopropyl alcohol or acetone antiseptic. Group I volunteers will have venous blood sampled after the sample site has dried at least 60 seconds after skin preparation. Group II volunteers will have venous blood sampled immediately while the skin site is moist with antiseptic.

Gas chromatography and ACA dehydrogenase methods will be used to determine acetone, isopropyl and ethyl alcohol concentrations.

Progress: Data have been collected and are currently being analyzed.

# Detail Summary Sheet

|  |                                  |                          |   |         |         |
|--|----------------------------------|--------------------------|---|---------|---------|
| Date:  | 2 Nov 83                         | Proj No:                 | C-11-83   | Status: | Ongoing |
| TITLE:   |                                  |                          |   |         |         |
| The Efficacy of MAST Trousers in the Prehospital Management of Penetrating Abdominal Injuries  |                                  |                          |   |         |         |
| Start Date   | 6 Jan 83                         | Est Comp Date:           | Jan 84  |         |         |
| Principal Investigator   | William Bickell, M.D., CPT, MC   | Facility                 | Brooke Army Medical Center                                    |         |         |
| Dept/Sec   | Department of Emergency Medicine | Associate Investigators: | Kenneth Mattox, M.D., Baylor College of Medicine, Houston, TX |         |         |
| Key Words:   | MAST                             |                          | Michael E. DeBakey  |         |         |
|  |                                  |                          | William Dice, M.D., MAJ, MC                                   |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:       | Periodic Review Results: |   |         |         |
| Objectives: To define the statistical significance of MAST trouser use in the prehospital management of penetrating abdominal injuries. Parameters to be examined include: 1) survival, 2) estimated blood loss, and 3) postoperative complications. |                                  |                          |   |         |         |

Technical Approach: Patients to be included in the study will be those patients stabilized and transported by the Houston Fire Department EMS to Ben Taub Emergency Room with the following: 1) penetrating wounds of the abdomen (defined superiorly by the zyphoid and costal margins and inferiorly by the iliac crests, inguinal ligament and symphysis pubis) and 2) systolic blood pressure equal to or less than 90 mm Hg.

Progress: Thus far approximately 200 patients have been entered on the study. It is anticipated that another 200 patients will be enrolled within the next 6-9 months. Analysis of data collected has not been done.

Detail Summary Sheet

|  |                            |                |         |         |         |
|--|----------------------------|----------------|---------|---------|---------|
| Date:  | 7 Oct 83                   | Proj No:       | C-23-80 | Status: | Ongoing |
| TITLE:   |                            |                |         |         |         |
| An Evaluation of Local Anesthetic Skin Testing and Progressive Challenge in Patients with a History of an Adverse Reaction to Local Anesthetics. |                            |                |         |         |         |
| Start Date   | 24 Jun 80                  | Est Comp Date: |         |         |         |
| Principal Investigator   | Facility                   |                |         |         |         |
| Daniel A. Ramirez, M.D., LTC, MC   | Brooke Army Medical Center |                |         |         |         |
| Dept/Sec   | Associate Investigators:   |                |         |         |         |
| Department of Medicine/Allergy-Immunology  |                            |                |         |         |         |
| Key Words:   |                            |                |         |         |         |
| Local anesthetic skin testing  |                            |                |         |         |         |
| Adverse reaction   |                            |                |         |         |         |

|  |                  |                          |
|--|------------------|--------------------------|
| Accumulative MEDCASE   | Est Accumulative | Periodic                 |
| Cost:  | OMA Cost:        | Review Results: Continue |
| Objective: To confirm the safety and usefulness of this approach in a larger number of patients with histories of previous suspected adverse reactions to local anesthetics. |                  |                          |

Technical Approach: Patients with histories of adverse reactions to local anesthetics are evaluated by a skin test progressive challenge protocol.

Progress: Patients continue to be entered and sent to a larger data base at Fitzsimons Army Medical Center. No adverse effects have been encountered.

# Detail Summary Sheet

Date: 12 Oct 83 Proj No: C-37-80 Status: Ongoing

## TITLE:

Assessment of Granulocyte Function and Serum Opsonic Capacity in Nephrology Patients Undergoing Dialysis

Start Date 28 Jul 80 Est Comp Date: Jul 84

Principal Investigator Facility

Charles S. Foulks, M.D., MAJ, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Medicine/Nephrology

## Key Words:

Dialysis

Granulocyte function

Accumulative MEDCASE Est Accumulative Periodic

Cost: OMA Cost: \$1,500 Review Results: Continue

Objective: To assess granulocyte function in nephrology patients undergoing dialysis.

Technical Approach: Blood samples are obtained from dialysis patients immediately prior to and after being exposed to the dialysis membrane during hemodialysis. The polymorphonuclear cells have been subjected to chemiluminescent studies.

Progress: A paper describing the basic concept and approach is in preparation.

# Detail Summary Sheet

|   |  |                             |                               |         |         |
|---|--|-----------------------------|-------------------------------|---------|---------|
| Date:   | 26 Oct 83                                  | Proj No:                    | C-2-81                        | Status: | Ongoing |
| TITLE: Evaluation of the Coagulation, Fibrinolytic, and Humoral Immune Abnormalities Induced by Crotalus Atrox (Western Diamondback Rattlesnake) Snakebite.                                 |  |                             |                               |         |         |
| Start Date  | 10 Oct 80                                  | Est Comp Date: Undetermined |                               |         |         |
| Principal Investigator  | John J. Posch, Jr., DAC                    |                             | Facility                      |         |         |
| Dep Sec   | Department of Medicine/Hematology-Oncology |                             | Brooke Army Medical Center    |         |         |
| Key Words:  | Snakebite                                  |                             | Associate Investigators:      |         |         |
| Envenomate  | Rattlesnake                                |                             | Glenn M. Mills, M.D., MAJ, MC |         |         |
|   |  |                             | Barbara Reeb, DAC             |         |         |
|   |  |                             | Thomas G. Glass, Jr., M.D.    |         |         |
| Accumulative MEDCASE  | Est Accumulative                           | Periodic                    |                               |         |         |
| Cost:   | OMA Cost: \$16,714                         | Review Results: Continue    |                               |         |         |
| Objective: To evaluate and characterize the coagulation, fibrinolytic and humoral immune abnormalities induced in patients envenomated by Crotalus atrox (western diamondback rattlesnake). |  |                             |                               |         |         |

**Technical Approach:** Coagulation profiles including fibrinolytic enzyme workups are being performed on plasma specimens collected from C. atrox snakebite victims. Additional plasma and serum aliquots collected when possible are stored for future chemiluminescence techniques or further coagulation testing. In vitro studies using crude venoms obtained from C. atrox snakes and from two close relatives, C. adamanteus and C. h. horridus have also been performed using tests modified to measure comparative chromogenic, procoagulant, and fibrinolytic activities. Venoms from different size groups of C. atrox snakes were evaluated and demonstrated significant differences between groups. Furthermore, several different enzymatic effects upon fibrinogen, plasmin, and prekallikrein have been noted. Some venoms contain both coagulant and fibrinolytic activities. Further isolation and characterization of the several enzymes implicated are being performed using electrophoretic and electrofocusing procedures as well as individual clotting, fibrinolytic, and chromogenic methods.

**Progress:** Coagulation profiles and fibrinolytic workups have been completed on 138 individually collected specimens from 54 different snakebite patients to date. Several others are waiting to be tested. Only 14 patients were added to the study this year, reflecting difficulty in obtaining specimens as well as a decrease in annual snakebite cases usually seen in this area. Coagulation abnormalities were detected in many of these cases and have been characterized. Although more additions to this study are desired, especially serially collected specimens obtained post bite up to the time of remission of symptoms, the present results of this group has been summarized and are being prepared for submission for publication.

# Detail Summary Sheet

|   |   |                          |   |         |         |
|---|---|--------------------------|---|---------|---------|
| Date:   | 27 Oct 83   | Proj No:                 | C-3-81  | Status: | Ongoing |
| TITLE:  |   |                          |   |         |         |
| Study of Granulocyte Function in Leukemia Patients Receiving Granulocyte Transfusions                     |   |                          |   |         |         |
| Start Date  | 10 Oct 81   | Est Comp Date:           |   |         |         |
| Principal Investigator  | Glenn M. Mills, M.D., MAJ, MC                               |                          | Facility  |         |         |
| Dept/Sec  | Department of Medicine/Hematology                           |                          | Brooke Army medical Center  |         |         |
| Key Words:  | Granulocyte function<br>Leukemia<br>Granulocyte transfusion |                          | Associate Investigators:<br>Donald C. Townsend, M.D., MAJ, MC<br>Robert C. Allen, M.D., Ph.D.,<br>MAJ, MC<br>Terry E. Pick, M.D., LTC, MC |         |         |
| Accumulative MEDCASE  | Est Accumulative  | Periodic                 |   |         |         |
| Cost:   | OMA Cost:   | Review Results: Continue |   |         |         |
| Objectives: Prospective evaluation of neutrophil function and humoral immunity in patients with leukemia. |   |                          |   |         |         |

Evaluation of changes induced in humoral immunity and neutrophil function by either radiation therapy or chemotherapy.

Evaluation of kinetics of transfused neutrophils in leukemia patients.

Correlation of improvement in neutrophil function and humoral immunity in recipients of granulocyte transfusions and clinical course.

Technical Approach: Baseline evaluation of the patient's humoral opsonic capacity will be performed. Granulocyte redox function will also be studied. Additional studies will be performed with routine CBCs during the induction phase of chemotherapy. Once a patient has entered remission of his leukemia, a repeat study will be performed on a monthly basis. Serum opsonic capacity and granulocyte redox function will be assayed by the micro technique of probe amplified chemiluminescence.

Progress: Attempts are still being made to perfect the assays to handle the volume of specimens this study will entail.

# Detail Summary Sheet

Date: 27 Oct 83 Proj No: C-5-81 Status: Ongoing

## TITLE:

The Natural History of Patients with Large Local Reactions (LLR)  
Following a Hymenoptera Sting

Start Date: 3 Feb 81 Est Comp Date: Sep 84

|  |  |
|--|--|
| Principal Investigator<br>Daniel A. Ramirez, M.D., LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department of Medicine/Allergy-Immunology      | Associate Investigators:               |

## Key Words:

Hymenoptera sting  
Large local reactions (LLR)

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: To study the natural history of patients who have experienced LLR following an insect sting. Several aspects of this problem will be studied:

- What is the risk of systemic anaphylaxis in this group of patients? and
- Can patients with histories of LLR and at risk of anaphylaxis be identified prospectively.

Technical Approach: Patients who meet the above objectives will undergo the following:

- Venom skin testing.
- Obtain venom specific IgE and IgG.
- Sting challenged under controlled conditions to assess current sensitivity.
- Obtain specific venom IgE and IgG's following sting challenge.

Progress: Considerable difficulty has been encountered in getting the micro-titer plate ELISA method to work for the measurement of specific IgE/IgG. To date possible participants in the study have only been identified--none have been stung.

The difficulties with the ELISA method now have been solved. As soon as the sera are analyzed, sting challenges are to be conducted. However, this challenge may be delayed until the summer of 1984 because of the supply of insects.

# Detail Summary Sheet

|   |                              |                 |          |         |            |
|---|------------------------------|-----------------|----------|---------|------------|
| Date:   | 27 Oct 83                    | Proj No:        | C-10-81  | Status: | Terminated |
| TITLE:  |                              |                 |          |         |            |
| Evaluation of the Complement System and Humoral Immunity in Patients Undergoing Fibrinolytic Therapy.                               |                              |                 |          |         |            |
| Start Date  | 3 Feb 81                     | Est Comp Date:  | Jun 82   |         |            |
| Principal Investigator  | Facility                     |                 |          |         |            |
| Glenn M. Mills, M.D., MAJ, MC   | Brooke Army Medical Center   |                 |          |         |            |
| Dept/Sec  | Associate Investigators:     |                 |          |         |            |
| Department of Medicine/Hematology-Oncology  | Robert C. Allen, M.D., Ph.D. |                 |          |         |            |
| Key Words:  | MAJ, MC                      |                 |          |         |            |
| Complement System   |                              |                 |          |         |            |
| Humoral immunity  |                              |                 |          |         |            |
| Fibrinolytic therapy  |                              |                 |          |         |            |
| Accumulative MEDCASE  | Est Accumulative             | Periodic        |          |         |            |
| Cost:   | OMA Cost:                    | Review Results: | Continue |         |            |
| Objective: To conduct a prospective evaluation of the effects of fibrinolytic therapy on the complement and humoral immune systems. |                              |                 |          |         |            |

Technical Approach: None.

Progress: This study was terminated due to inadequate number of patients. The original plan was to study 20 patients; however, only five were enrolled.



# Detail Summary Sheet

|  |  |                          |                              |         |         |
|--|--|--------------------------|------------------------------|---------|---------|
| Date:  | 28 Oct 83                                  | Proj No:                 | C-12-81                      | Status: | Ongoing |
| TITLE:   |  |                          |                              |         |         |
| Study of Granulocyte Function, Complement Activity and Coagulation in Patients with the Adult Respiratory Distress Syndrome (ARDS) |  |                          |                              |         |         |
| Start Date   | 4 Feb 81                                   | Est Comp Date: Jun 84    |                              |         |         |
| Principal Investigator   | Glenn M. Mills, M.D., MAJ, MC              |                          | Facility                     |         |         |
| Dept/Sec   | Department of Medicine/Hematology-Oncology |                          | Brooke Army Medical Center   |         |         |
| Key Words:   | ARDS                                       |                          | Associate Investigators:     |         |         |
| Complement   | Granulocyte-induced endothelial damage     |                          | Robert C. Allen, M.D., Ph.D. |         |         |
|  |  |                          | MAJ, MC                      |         |         |
| Accumulative MEDCASE   | Est Accumulative                           | Periodic                 |                              |         |         |
| Cost:  | OMA Cost:                                  | Review Results: Continue |                              |         |         |
| Objectives: Evaluation of neutrophil metabolism by chemiluminescence in patients with ARDS.  |  |                          |                              |         |         |

Measurement of complement activity via the classical and alternate pathways in patients with ARDS.

Study of the coagulation and fibrinolytic systems in patients with ARDS.

Correlation of steroid therapy with the above objectives in patients with ARDS.

Technical Approach: Adequate number of patients have been entered on the study. No new patients entered this Fiscal Year. Documentation has been completed that heparin does not alter coagulation parameters.

Progress: Coagulation testing and screening has been completed as have most of immunology assays. Completion of study is anticipated in near future.

# Detail Summary Sheet

Date: 28 Oct 83 Proj No: C-29-81 Status: Terminated

TITLE: Treatment of Severe Erythema Multiforme with Systemic Steroids

|                        |                                    |  |
|------------------------|------------------------------------|--|
| Start Date             | 3 Apr 81                           | Est Comp Date:   |
| Principal Investigator | Charles W. Lewis, M.D., COL, MC    | Facility   |
| Dept/Sec               | Department of Medicine/Dermatology | Brooke Army Medical Center   |
| Key Words:             | Erythema multiforme<br>Steroids    | Associate Investigators:<br>Nancy D'Silva, M.D., CPT, MC<br>Eric W. Kraus, M.D., LTC, MC |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objective: To determine if Prednisone is effective in the treatment of severe erythema multiforme. |                            |                          |

Technical Approach: No patients have been entered on this study.

Progress: Study terminated because of inability to accrue patients to study.

# Detail Summary Sheet

|   |           |                  |                            |                          |         |
|---|-----------|------------------|----------------------------|--------------------------|---------|
| Date:   | 28 Oct 83 | Proj No:         | C-31-81                    | Status:                  | Ongoing |
| TITLE:  |           |                  |                            |                          |         |
| Profile of Aortic Impedance in Patients with Congestive Cardiomyopathy  |           |                  |                            |                          |         |
| Start Date  |           |                  | 11 May 81                  |                          |         |
| Principal Investigator  |           |                  | Est Comp Date: Unknown     |                          |         |
| Joseph P. Murgo, M.D., COL, MC  |           |                  | Facility                   |                          |         |
| Dept/Sec  |           |                  | Brooke Army Medical Center |                          |         |
| Department of Medicine/Cardiology   |           |                  | Associate Investigators:   |                          |         |
| Key Words:  |           |                  | N. Westerhoff, Ph.D.       |                          |         |
| Aortic impedance  |           |                  | B. J. Rubal, Ph.D.         |                          |         |
| Congestive cardiomyopathy   |           |                  |                            |                          |         |
| Cardiac catheterization   |           |                  |                            |                          |         |
| Accumulative MEDCASE  |           | Est Accumulative |                            | Periodic                 |         |
| Cost:   |           | OMA Cost:        |                            | Review Results: Continue |         |
| Objective: To evaluate the role of afterload reduction and exercise on the aortic impedance profile of patients with congestive cardiomyopathy. |           |                  |                            |                          |         |

Technical Approach: Multisensor pressure/velocity catheters are used to obtain the aortic impedance spectra of patients with congestive cardiomyopathy prior to and following afterload reduction therapy and exercise.

Progress: Because of strict patient selection requirements, no new patients have been entered into study FY 83.

# Detail Summary Sheet

Date: 28 Oct 83 Proj No: C-33-81 Status: Ongoing

## TITLE:

Renal Function in Primary Hyperparathyroidism.

|                                   |                            |                            |          |
|-----------------------------------|----------------------------|----------------------------|----------|
| Start Date                        | 12 May 81                  | Est Comp Date:             | May 84   |
| Principal Investigator            | (vice Wright)              | Facility                   |          |
| Charles J. Foulks, M.D., MAJ, MC  |                            | Brooke Army Medical Center |          |
| Dept/Sec                          |                            | Associate Investigators:   |          |
| Department of Medicine/Nephrology |                            |                            |          |
| Key Words:                        |                            |                            |          |
| Hyperparathyroidism               |                            |                            |          |
| Renal function                    |                            |                            |          |
| Accumulative MEDCASE Cost:        | Est Accumulative OMA Cost: | Periodic Review Results:   | Continue |

Objective: To gather detailed information about renal function in patients with primary hyperparathyroidism at the time of diagnosis, and to follow these functions serially in patients not undergoing surgery. These data should permit a more precise estimate of the risk of "medical" therapy versus "surgical" therapy in patients with mild, asymptomatic, primary hyperparathyroidism.

Technical Approach: All patients have submitted 24-hour urines for creatinine clearance, calcium phosphate excretion, and sodium balance while on a 3-gram sodium 400 mg calcium diet. Following this, all patients had determination of the proximal tubular reabsorptive threshold for bicarbonate by hypertonic sodium bicarbonate infusion, determination of distal tubular acidification mechanisms by an oral ammonium chloride loading, determination of concentrating ability of the kidney by overnight deprivation test, and determination of maximal dilution of the kidney during water loading. Bone scanning, long bone films, skull and distal clavicular films are done at each testing. Patients have also had red cell osmotic fragility studies.

Progress: To date, 13 patients have been studied. One has been removed from the study group because of development of symptomatic atherosclerotic cardiovascular disease with angina. Two have been lost to follow-up, and one has been submitted for parathyroidectomy because of deterioration of bone films. It is interesting to note that in the single patient who has required parathyroidectomy because of progressive bone disease, she developed a proximal tubular renal tubular acidosis with a depressed reabsorptive transport maximum for bicarbonate. At this point, 10 patients remain in the study group being followed on a serial basis. At present, bone films, bone scans and serum electrolytes are being done on a every 6-month basis. It is suspected that there will be a deterioration in the electrolytes at the time the urinary abnormalities are found, and it should be about the same time bone film abnormalities are seen.

# Detail Summary Sheet

|  |   |                          |                          |  |         |
|--|---|--------------------------|--------------------------|--|---------|
| Date:  | 21 Oct 83                                     | Proj No:                 | C-34-81                  | Status:  | Ongoing |
| TITLE:   |   |                          |                          |  |         |
| The Effect of Propranolol on Cardiac Ejection Fractions as Determined by Gated Scans in Thyrotoxic Patients. |   |                          |                          |  |         |
| Start Date   | 15 Jun 81                                     | Est Comp Date:           | Jun 83                   |  |         |
| Principal Investigator   | Thomas J. Taylor, M.D., MAJ, MC               |                          | Facility                 | Brooke Army Medical Center                                       |         |
| Dept/Sec   | Department of Medicine/Endocrinology          |                          | Associate Investigators: | Robert J. Telepak, M.D., LTC, MC<br>Steven Bunker, M.D., MAJ, MC |         |
| Key Words:   | Propranolol<br>Thyrotoxic<br>Cardiac ejection |                          |                          |  |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:                    | Periodic Review Results: | Continue                 |  |         |

Objective: To study the effects of Propranolol on cardiac ejection fractions in thyrotoxic patients and thereby critically assess the relative merits of this mode of therapy.

Technical Approach: MUGA studies are used to evaluate cardiac parameters in thyrotoxic patients before and after administration of Propranolol.

Progress: One patient has been entered on the study during FY 83. We are now restudying data with a new MUGA analysis.

# Detail Summary Sheet

|   |                                  |                          |          |         |         |
|---|----------------------------------|--------------------------|----------|---------|---------|
| Date:   | 31 Oct 83                        | Proj No:                 | C-35-81  | Status: | Ongoing |
| TITLE:  |                                  |                          |          |         |         |
| Hepatic Artery Embolization in the Management of Primary or Metastatic Hepatic Neoplasm                         |                                  |                          |          |         |         |
| Start Date  | 15 Jun 81                        | Est Comp Date:           | Jun 84   |         |         |
| Principal Investigator  | Facility                         |                          |          |         |         |
| Walter H. Harvey, M.D., MAJ, MC   | Brooke Army Medical Center       |                          |          |         |         |
| Dept/Sec  | Associate Investigators:         |                          |          |         |         |
| Department of Medicine/Oncology   | J. Dean McCracken, M.D., COL, MC |                          |          |         |         |
| Key Words:  |                                  |                          |          |         |         |
| Hepatic artery embolization   |                                  |                          |          |         |         |
| Hepatic neoplasm  |                                  |                          |          |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:       | Periodic Review Results: | Continue |         |         |
| Objectives: To determine the response rate of hepatic embolization of primary or metastatic neoplasia in liver. |                                  |                          |          |         |         |

To evaluate the morbidity of hepatic embolization.

To evaluate the response rates of patients undergoing embolization with metastatic disease to liver to a historical control group.

Technical Approach: Patients with metastatic or primary neoplasm in liver undergo percutaneous hepatic artery catheter placement confirmed by angiography. When catheter placement is corrected, embolization is carried out by injecting Ivalon<sup>R</sup> (polyvinyl particles) embolization of right and left hepatic arteries.

Progress: To date twenty-six patients have undergone 29 embolization procedures. No deaths directly related to embolization have occurred.

Review of all patients, toxicity, response - as to median response duration and survival from time of embolization. - are in the process of being reviewed.

# Detail Summary Sheet

|  |                  |                 |                             |         |           |
|--|------------------|-----------------|-----------------------------|---------|-----------|
| Date:  | 31 Oct 83        | Proj No:        | C-36-81                     | Status: | Completed |
| TITLE: Comparison of Gray-Scale Ultrasonography and Computed Tomography with Infusion Nephrotomogram in Early Diagnosis of Adult-type Polycystic Kidney Disease  |                  |                 |                             |         |           |
| Start Date   |                  |                 | 15 Jun 81                   |         |           |
| Principal Investigator   |                  |                 | Est Comp Date:              |         |           |
| Lucius F. Wright, M.D., MAJ, MC  |                  |                 | Facility                    |         |           |
| Dept/Sec   |                  |                 | Brooke Army Medical Center  |         |           |
| Department of Medicine/Nephrology  |                  |                 | Associate Investigators:    |         |           |
| Key Words:   |                  |                 | Harold Cable, M.D., CPT, MC |         |           |
| Polycystic kidney disease  |                  |                 |                             |         |           |
| Gray-scale ultrasonography   |                  |                 |                             |         |           |
| Computed tomography  |                  |                 |                             |         |           |
| Nephrotomogram   |                  |                 |                             |         |           |
| Accumulative MEDCASE   | Est Accumulative | Periodic        |                             |         |           |
| Cost:  | OMA Cost:        | Review Results: |                             |         |           |
| Objective: To compare gray-scale ultrasonography and abdominal computed tomography to infusion nephrotomography in establishing the diagnosis of adult-type polycystic kidney disease in asymptomatic persons at risk. |                  |                 |                             |         |           |

Technical Approach: Patients agreeing to enter into the study underwent a complete history and physical examination. Blood was obtained for complete blood count and standard serum chemistries to include creatinine, BUN and electrolytes. Urinalysis was performed on two separate occasions and two urine cultures were obtained. Creatinine clearance protein excretion were determined on a 24 hour urine collection obtained during a period of forced hydration.

Ultrasound examination of both kidneys was performed on either a Technicon Auto-Sector real time using 3-5 mH<sub>2</sub> transducer or Pinkar 80-L Digital B scanner. CT scans were performed on a GE8800 using serial 1.0 cm sections through the kidneys. The patients were then given Renograffin 60, 1 ml/kg body weight to a maximal dose of 50 ml by intravenous infusion, and nephrotomograms were obtained using a standard polytome and 1.0 slices. A second CT scan was then performed while contrast was still present.

Progress: Fifteen patients, eleven females and four males of mean age 14.6 years agreed to enter the study. Serum chemistries and creatinine clearance were normal in all patients. Protein excretion was less than 150 mg per 24 hours in all patients.

Nine patients had sonographic evidence of cysts. Eight of these patients had positive CT scans, but only five had positive nephrotomograms. No patient with a positive nephrotomogram or CT scan had a negative ultrasound.

C-36-81 (continued)

Five patients with a positive sonogram complained of intermittent flank and loin pain, usually exacerbated by exercise. Four of these patients had a history of documented urinary tract infection. The other patient had a history of gross hematuria.

The presence of a murmur in the six oldest patients was evaluated by echocardiogram, and all were shown to have mitral valve prolapse. Five of these patients had evidence of PCKD.



# Detail Summary Sheet

|   |                                   |                                 |                            |         |            |
|---|-----------------------------------|---------------------------------|----------------------------|---------|------------|
| Date:   | 31 Oct 83                         | Proj No:                        | C-42-81                    | Status: | Terminated |
| TITLE:  |                                   |                                 |                            |         |            |
| Effects of Dietary Sodium and Potassium Intake upon the Response of the Conscious Dog to Acute Hyperkalemia: The Quantitative Role of the Liver |                                   |                                 |                            |         |            |
| Start Date  | 15 Jun 81                         | Est Comp Date:                  |                            |         |            |
| Principal Investigator  | Charles J. Foulks, M.D., MAJ, MC  |                                 | Facility                   |         |            |
| Dept/Sec  | Department of Medicine/Nephrology |                                 | Brooke Army Medical Center |         |            |
| Key Words:  | Hyperkalemia                      |                                 | Associate Investigators:   |         |            |
|   |                                   | Lucius F. Wright, M.D., MAJ, MC |                            |         |            |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:        | Periodic Review Results:        |                            |         |            |
| Objective: To study the quantitative role of the liver in the homeostasis response of a conscious dog to acute hyperkalemia.                    |                                   |                                 |                            |         |            |

Technical Approach: The approach used involves quantitatively time integrated response of serum potassium to infusion of potassium under a variety of metabolic circumstances. In an effort to develop data on the quantitative role in the liver and maintenance of internal homeostasis and protection against acute hyperkalemia, cannulas will be placed to permit sampling of the portal and hepatic vein. The technical approach has not varied from that described in the original clinical investigation protocol.

Progress: Following the departure of the associate investigator, the study was terminated because of the additional clinical and administrative duties of the principal investigator.

# Detail Summary Sheet

Date: 31 Oct 83 Proj No: C-52-81 Status: Ongoing

## TITLE:

Effect of Aspirin (ASA) on Airway Responses

|   |                            |                          |          |
|---|----------------------------|--------------------------|----------|
| Start Date                                | 7 Jul 81                   | Est Comp Date:           | Jul 84   |
| Principal Investigator                    | Facility                   |                          |          |
| Daniel A. Ramirez, M.D., LTC, MC          | Brooke Army Medical Center |                          |          |
| Dept/Sec                                  | Associate Investigators:   |                          |          |
| Department of Medicine/Allergy-Immunology |                            |                          |          |
| Key Words:                                |                            |                          |          |
| Nonallergic rhinitis                      |                            |                          |          |
| Aspirin                                   |                            |                          |          |
| Accumulative MEDCASE Cost:                | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |

Objective; To investigate the effects of aspirin on airway responses in man. Specifically the following questions will be answered: a. What effect does ASA have on upper and lower airway resistance in patients with nonallergic rhinitis with eosinophilia (NARES)? and b. Are patients with NARES - or any identifiable subset thereof - at particular risk of developing lower airway obstruction from aspirin?

Technical Approach: Subjects are to be challenged with 10 grains of aspirin and their nasal airway resistance and pulmonary functions will be measured and followed.

Progress: All of the necessary hardware for the measurement of nasal airway resistance is now available. Prospective patients are now being identified, and the study will commence very shortly.

# Detail Summary Sheet

Date: 31 Oct 83 Proj No: C-54-81 Status: Terminated

## TITLE:

Phosphate Homeostasis in the Normal and Renal Failure Dogs

|                                   |                                  |
|-----------------------------------|----------------------------------|
| Start Date 6 Aug 81               | Est Comp Date:                   |
| Principal Investigator            | Facility                         |
| Lucius F. Wright, M.D., MAJ, MD   | Brooke Army Medical Center       |
| Dept/Sec                          | Associate Investigators:         |
| Department of Medicine/Nephrology | Charles J. Foulks, M.D., MAJ, MC |
| Key Words:                        |                                  |
| Homeostasis                       |                                  |
| Renal failure                     |                                  |

|                      |                   |                 |
|----------------------|-------------------|-----------------|
| Accumulative MEDCASE | Est Accumulative  | Periodic        |
| Cost:                | OMA Cost: \$5,342 | Review Results: |

Objective: To define the kinetics of phosphate elimination in response to a number of maneuvers in normal dogs and in dogs with experimentally induced reductions in renal failure. These data will be used to examine the hypothesis that secondary hyperparathyroidism develops in early renal failure as a consequence of the need to amplify the renal excretory response to phosphate loading that occurs as an inevitable result of eating.

Technical Approach: None.

Progress: Study terminated due to release from active duty of the principal investigator.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-58-81 Status: Ongoing  
 TITLE:

The Specificity of the Priming on the Nasal Mucous Membranes by Allergens and the Effect of Pharmacological Intervention

|  |  |
|--|--|
| Start Date 20 Aug 81                                       | Est Comp Date: Aug 84                                      |
| Principal Investigator<br>Daniel A. Ramirez, M.D., LTC, MC | Facility<br>Brooke Army Medical Center                     |
| Dept/Sec<br>Department of Medicine/Allergy-Immunology      | Associate Investigators:<br>Gwenesta Melton, M.D., CPT, MC |
| Key Words:<br>Allergen<br>Nasal mucous membranes           |  |

|   |                               |                                      |
|---|-------------------------------|--------------------------------------|
| Accumulative MEDCASE<br>Cost:   | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: Continue |
| Objective: To investigate further the phenomena of mucous membrane priming by antigens. Several aspects of the problem will be studied: a. Does it occur in different aeroallergen systems? b. Is the priming effect on the nasal mucosa specific for the allergen that induces it? c. What is the effect, if any, of antihistamines, intranasal corticosteroids and cromolyn sodium on nasal priming? d. Is the priming effect due to an increase of specific IgE? |                               |                                      |

Technical Approach: Study subjects will be challenged intranasally to the appropriate allergens over successive days to prime their mucus. By challenging with a different allergen to which the patient is also resistive, we will determine if the phenomenon is specific or not. Also, antihistamines, corticosteroids and cromolyn sodium will be used prior to the study to determine whether priming can be pharmacologically inhibited. Specific IgE (by RAST) will then be obtained.

Progress: All the necessary hardware is now available. Prospective patients are being identified, and the study will commence very shortly.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-1-82 Status: Ongoing

## TITLE:

Chronic Cardiopulmonary Adaptations in Pentathlon Athletes

|  |  |
|--|--|
| Start Date 21 Oct 81                                   | Est Comp Date: Jan 84  |
| Principal Investigator<br>Bernard J. Rubal, Ph.D., dac | Facility<br>Brooke Army Medical Center   |
| Dept/Sec<br>Department of Medicine/Cardiology          | Associate Investigators:<br>Joseph P. Murgu, M.D., COL, MC<br>Stuart Damore, M.D., MAJ, MC |
| Key Words:<br>Athletic heart syndrome                  |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: To identify the risk and/or benefits of long-term, intense endurance training and to examine the cardiovascular adaptations associated with athletic training.

Technical Approach: Noninvasive cardiac evaluations have been performed on 10 male and 10 female members of the Modern Pentathlon team. Cardiac structural changes have been compared with age and body size matched control subjects.

Progress: The chronic cardiac adaptation associated with endurance conditioning include eccentric hypertrophic changes and normal myocardial systolic function and perfusion at rest and during exercise. Pentathletes who will compete in the Olympic games will be retested to quantify cardiac performance at peak conditioning. Except for Olympic contenders, all data for this study has been collected and is being statistically evaluated.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-3-82 Status: Ongoing

## TITLE:

Assessment of Sunscreen Substantivity

|  |   |
|--|---|
| Start Date 21 Oct 81                                   | Est Comp Date: Unknown  |
| Principal Investigator<br>Eric W. Kraus, M.D., LTC, MC | Facility<br>Brooke Army Medical Center  |
| Dept/Sec<br>Department of Medicine/Dermatology         | Associate Investigators:<br>Martha McCollough, M.D.<br>James Keeling, M.D., MAJ, MC |
| Key Words:<br>Sunscreen<br>Substantivity               |   |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: To compare the protection offered by sunscreens after swimming with that achieved when not exposed to water.

Technical Approach: Twenty-nine subjects volunteered for the determination of SPF and water resistance property of ten sunscreen formulations. Each volunteer had three products applied topically on the right side of back prior to a 40 minute swim. The left side then had the identical products applied. This was followed by a total sun exposure of 12 MED, and patient's backs were then examined for erythema at 24 and 48 hours. There were no serious adverse effects or physical injuries from the study.

Progress: This study was done in conjunction with Harvard Medical School. The final results are being compiled at this time.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-8-82 Status: Terminated

## TITLE:

The Effect of Cimetidine on Acetaminophen (Tylenol).

|   |           |                            |
|---|-----------|----------------------------|
| Start Date                              | 21 Oct 81 | Est Comp Date:             |
| Principal Investigator                  |           | Facility                   |
| Rolando R. Longoria, M.D., CPT, MC      |           | Brooke Army Medical Center |
| Dept/Sec                                |           | Associate Investigators:   |
| Department of Medicine/Gastroenterology |           |                            |
| Key Words:                              |           |                            |
| Cimetidine                              |           |                            |
| Acetaminophen                           |           |                            |

|                      |                  |                 |
|----------------------|------------------|-----------------|
| Accumulative MEDCASE | Est Accumulative | Periodic        |
| Cost:                | OMA Cost:        | Review Results: |

Objective: To investigate the effects of cimetidine and acetaminophen in healthy subjects.

Technical Approach: None.

Progress: Study terminated due to PCS of principal investigator.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-10-82 Status: Ongoing  
 TITLE:

Effects of Asynchronous and Nonhomogeneous Regional Function on Global Parameters

|   |  |
|---|--|
| Start Date 18 Nov 81                                      | Est Comp Date: Unknown   |
| Principal Investigator<br>William E. Craig, M.D., MAJ, MC | Facility<br>Brooke Army Medical Center   |
| Dept/Sec<br>Department of Medicine/Cardiology             | Associate Investigators:<br>Ares D. Pasipoularides, M.D., Ph.D.<br>Massimo Pagani, M.D., Universita<br>de Milano, Milan, Italy |
| Key Words:<br>Ventricular performance                     |  |

|   |                            |                          |
|---|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To establish a model for nonhomogeneous, segmental contraction and relaxation patterns in the chronically instrumented conscious dog. |                            |                          |

To use the model to further understand and evaluate the abnormalities of diastolic function similar to those seen in clinical disease states.

Technical Approach: This study was conducted in collaboration with the Institute of Cardiovascular Research in Milan, Italy. Data obtained from instrumented conscious dogs is analyzed by computer techniques to assess models for ventricular relaxation.

Progress: Data obtained thus far has shown that asynchrony of left ventricular contraction and relaxation precludes the use of global parameters of relaxation which are currently used.



# Detail Summary Sheet

|   |                            |                                   |         |         |         |
|---|----------------------------|-----------------------------------|---------|---------|---------|
| Date:   | 1 Nov 83                   | Proj No:                          | C-11-82 | Status: | Ongoing |
| TITLE: Open, Single-Dose Evaluation of Resting Hemodynamic Effects of Oral Nifedipine in Patients with Hypertrophic Cardiomyopathy and Acquired Left Ventricular Hypertrophy. |                            |                                   |         |         |         |
| Start Date  | 4 Dec 81                   | Est Comp Date: Dec 83             |         |         |         |
| Principal Investigator  |                            | Facility                          |         |         |         |
| William E. Craig, M.D., MAJ, MC   |                            | Brooke Army Medical Center        |         |         |         |
| Dept/Sec  |                            | Associate Investigators:          |         |         |         |
| Department of Medicine/Cardiology   |                            | Joseph P. Murgu, M.D., COL, MC    |         |         |         |
| Key Words:  |                            |                                   |         |         |         |
| Cardiomyopathy  |                            |                                   |         |         |         |
| Ventricular hypertrophy   |                            |                                   |         |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: Continue |         |         |         |
| Objective: To evaluate the effects of Nifedipine on resting hemodynamics in patients with hypertrophic cardiomyopathy and acquired left ventricular hypertrophy.              |                            |                                   |         |         |         |

Technical Approach: This study is being performed in collaboration with the Harvard Medical School. Patients undergoing catheterization with a diagnosis of hypertrophic cardiomyopathy are evaluated by pressure and echocardiographic techniques during rest, Nitroprusside infusion, and following oral Nifedipine therapy.

Progress: No adverse effects have been sustained as a result of participation in the study. Data obtained both at Brooke Army Medical Center and the Harvard Medical School indicate that Nifedipine has a direct myocardial effect to improve diastolic function in addition to the benefit obtained after load reduction.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-13-82 Status: Ongoing

## TITLE:

Intracardiac Pressure and Flow Changes Following Amyl Nitrite Inhalation

|  |   |
|--|---|
| Start Date 8 Jan 82  | Est Comp Date: Jun 84                               |
| Principal Investigator (vice Moody)<br>Steven R. Bailey, M.D., MAJ, MC | Facility<br>Brooke Army Medical Center              |
| Dept/Sec<br>Department of Medicine/Cardiology                          | Associate Investigators:<br>B. J. Rubal, DAC, Ph.D. |
| Key Words:<br>Amyl Nitrite<br>Intracardiac pressure                    |   |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: To better understand the hemodynamic events responsible for the auscultatory changes following amyl nitrite inhalation in normal man.

Technical Approach: Patients undergoing cardiac catheterization for clinical indications receive additional hemodynamic evaluation following amyl nitrite inhalation in addition to the usual hemodynamics obtained in the cardiac catheterization laboratory.

Progress: This study has not been completely implemented because of transfer of the principal investigator.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-15-82 Status: Terminated

## TITLE:

Percutaneous Transluminal Coronary Angioplasty, a Prospective Study on Its Indications, Use, and Efficacy

|                                   |           |                            |
|-----------------------------------|-----------|----------------------------|
| Start Date                        | 19 Jan 82 | Est Comp Date:             |
| Principal Investigator            |           | Facility                   |
| Richard A. Schatz, M.D., MAJ, MC  |           | Brooke Army Medical Center |
| Dept/Sec                          |           | Associate Investigators:   |
| Department of Medicine/Cardiology |           |                            |
| Key Words:                        |           |                            |
| Angioplasty                       |           |                            |
| Coronary artery disease           |           |                            |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To evaluate coronary angioplasty in selected patients with coronary artery disease as an alternative to surgical revascularization.

Technical Approach: None.

Progress: Following approval, it was determined that this procedure was not considered experimental. Therefore the protocol was terminated.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-24-82 Status: Ongoing

## TITLE:

Duration of Nosocomial Oropharyngeal Colonization Following Hospitalization

|                        |   |                          |                             |
|------------------------|---|--------------------------|-----------------------------|
| Start Date             | 9 Mar 82                                  | Est Comp Date:           | Jun 84                      |
| Principal Investigator | Charles E. Davis, M.D., CPT, MC           | Facility                 | Brooke Army Medical Center  |
| Dept/Sec               | Department of Medicine/Infectious Disease | Associate Investigators: | C. Kenneth McAllister, M.D. |
| Key Words:             | Pharyngeal flora                          |                          | LTC, MC                     |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objective: To determine the duration of the changed pharyngeal flora (gram negative rods and Staph aureus) acquired by hospitalized patients.

Technical Approach: Throat culture will be performed on hospitalized patients. Only those patients who become colonized will be allowed to continue. Cultures will be done weekly post-discharge until the normal (immediate hospitalization) flora returns.

Knowing the duration of colonization is crucial in approaching a recently discharged patient who now presents with pneumonia.

Progress: None at this time; however, it is anticipated that patients will soon be enrolled on the study.

# Detail Summary Sheet

|   |                                       |                          |          |         |         |
|---|---------------------------------------|--------------------------|----------|---------|---------|
| Date:   | 1 Nov 83                              | Proj No:                 | C-27-84  | Status: | Ongoing |
| TITLE:  |                                       |                          |          |         |         |
| The Role of Patient Education in Diabetes Care Utilizing Video Disc and Computer Technology   |                                       |                          |          |         |         |
| Start Date  | 5 Mar 82                              | Est Comp Date:           | Sep 84   |         |         |
| Principal Investigator  | Facility                              |                          |          |         |         |
| Thomas J. Taylor, M.D., MAJ, MC   | Brooke Army Medical Center            |                          |          |         |         |
| Dept/Sec  | Associate Investigators:              |                          |          |         |         |
| Department of Medicine/Endocrinology  | William J. Georgitis, M.D., MAJ, MC   |                          |          |         |         |
| Key Words:  | James H. Anderson, Jr., M.D., LTC, MC |                          |          |         |         |
| Diabetes  |                                       |                          |          |         |         |
| Computer technology   |                                       |                          |          |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:            | Periodic Review Results: | Continue |         |         |
| Objective: A video disc program is available that provides comprehensive diabetes education. We intend to evaluate the role of this teaching program in improving patient compliance and patient understanding of diabetes. |                                       |                          |          |         |         |

Technical Approach: Statistically significant patient knowledge exams will be given to patients utilizing various methods of education including video disc programs.

Progress: The audio-visual device is in place. We now await a nurse educator.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-28-82 Status: Ongoing  
 TITLE:

The Dose of Venom in Polistes Hypersensitivity

|   |                  |                            |
|---|------------------|----------------------------|
| Start Date  | 5 May 82         | Est Comp Date: Unknown     |
| Principal Investigator  |                  | Facility                   |
| Daniel A. Ramirez, M.D., LTC, MC  |                  | Brooke Army Medical Center |
| Dept/Sec  |                  | Associate Investigators:   |
| Department of Medicine/Allergy-Immunology   |                  |                            |
| Key Words:  |                  |                            |
| Polistes venom  |                  |                            |
| Immunotherapy   |                  |                            |
| Accumulative MEDCASE  | Est Accumulative | Periodic                   |
| Cost:   | OMA Cost:        | Review Results: Continue   |
| Objective: To determine whether the current recommended dose of venom (100 mcg) is appropriate for polistes sensitive patients. |                  |                            |

Technical Approach: Patients who currently receive recommended dose of polistes venom immunotherapy (100 mcg) are candidates for this study. They will be evaluated by drawing venom specific IgE/IgG and by a controlled sting challenge in the hospital.

Progress: In cooperation with the Allergy-Immunology Service at Wilford Hall Air Force Medical Center, an assay for venom specific IgE/IgG has been set up. This uses the ELISA technique. Candidates for the study are now being bled for antibody titer determinations before formally enrolling into the study and proceeding with the sting challenge.

# Detail Summary Sheet

|  |  |                             |  |         |         |
|--|--|-----------------------------|--|---------|---------|
| Date:  | 1 Nov 83   | Proj No:                    | C-29-82  | Status: | Ongoing |
| TITLE:   |  |                             |  |         |         |
| A Comparison of the Accuracy of the Sphygomomanometric and Oscillometric Blood Pressure Measuring Techniques |  |                             |  |         |         |
| Start Date   | 6 May 82   | Est Comp Date: Undetermined |  |         |         |
| Principal Investigator   | William R. Cox, M.D., CPT, MC                                  |                             | Facility   |         |         |
| Dept/Sec   | Department of Medicine/Cardiology                              |                             | Brooke Army Medical Center   |         |         |
| Key Words:   | Micromanometers<br>sphygmomanometer<br>Cardiac catheterization |                             | Associate Investigators:<br>Bernard J. Rubal, Ph.D., DAC<br>Southwest Research Institute |         |         |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To compare the systolic, diastolic and mean blood pressure obtained by sphygmomanometry and oxillometry with an intravascular measurement of blood pressure obtained by high fidelity micromanometry during cardiac catheterization.

To evaluate the effect of occlusion cuff length on the accuracy of the noninvasive measurement of blood pressure.

Technical Approach: To date, 18 patients have been studied. Noninvasive blood pressure is recorded simultaneously with invasive blood pressure during cardiac catheterization.

Progress: Data collection continues. Preliminary data analysis is planned in the near future.

# Detail Summary Sheet

|   |   |                          |                          |                                 |         |
|---|---|--------------------------|--------------------------|---------------------------------|---------|
| Date:   | 1 Nov 83                                    | Proj No:                 | C-31-82                  | Status:                         | Ongoing |
| TITLE:  |   |                          |                          |                                 |         |
| Evaluation of a Non-Invasive Strategy for the Diagnosis of Coronary Artery Disease  |   |                          |                          |                                 |         |
| Start Date  | 18 May 82                                   | Est Comp Date:           | Nov 84                   |                                 |         |
| Principal Investigator  | David L. Brown, M.D., MAJ, MC               |                          | Facility                 | Brooke Army Medical Center      |         |
| Dept/Sec  | Department of Medicine/Cardiology           |                          | Associate Investigators: | William E. Craig, M.D., MAJ, MC |         |
| Key Words:  | Cardiokymography<br>Coronary artery disease |                          |                          |                                 |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:                  | Periodic Review Results: | Continue                 |                                 |         |
| Objective: To evaluate the predictive value of a specific sequence of non-invasive tests to determine the probability of coronary artery disease in patients prior to selective coronary angiography. |   |                          |                          |                                 |         |

Technical Approach: Patients undergoing cardiac catheterization are also subjected to cardiokymography. Thus far, seven patients have been studied, three in Fiscal Year 83.

Progress: An increase in the number of technicians has improved the quality of recorded data. It is too early to report any significant findings.



# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-35-82 Status: Terminated

## TITLE:

Pneumococcal Meningitis

|                            |   |                            |
|----------------------------|---|----------------------------|
| Start Date                 | 18 May 82                                 | Est Comp Date:             |
| Principal Investigator     | C. Kenneth McAllister, M.D , LTC, MC      | Facility                   |
| Dept/Sec                   | Department of Medicine/Infectious Disease | Brooke Army Medical Center |
| Key Words:                 | Pneumococcal meningitis                   | Associate Investigators:   |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:                | Periodic Review Results:   |

Objectives: To retrospectively review the US Army experience in the management of penumococcal meningitis.

Analyze the potential morbidity and mortality among active duty US Army personnel with pneumococcal meningitis.

To determine whether or not the pneumococcal vaccine would be of potential benefit to active duty personnel.

Technical Approach: None.

Progress: This study was never undertaken due to inadequate information available through the computer printouts available.

# Detail Summary Sheet

|  |  |                                   |   |         |         |
|--|--|-----------------------------------|---|---------|---------|
| Date:  | 1 Nov 83                                 | Proj No:                          | C-37-82   | Status: | Ongoing |
| TITLE:   |  |                                   |   |         |         |
| Evaluation of Sodium Iodate as an Adjunctive Therapy to Radioactive Iodine for Graves' Hyperthyroidism   |  |                                   |   |         |         |
| Start Date   | 7 Jul 82                                 | Est Comp Date: Unknown            |   |         |         |
| Principal Investigator   | Thomas J. Taylor, M.D., MAJ, MC          |                                   | Facility  |         |         |
| Dept/Sec   | Department of Medicine/Endocrinology     |                                   | Brooke Army Medical center  |         |         |
| Key Words:   | Graves' hyperthyroidism<br>Sodium Iodate |                                   | Associate Investigators:<br>William J. Georgitis, M.D., MAJ, MC<br>Robert Telepak, M.D., LTC, MC<br>Steven Bunker, M.D., MAJ, MC<br>Michael Hartshorne, M.D., MAJ, MC |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:               | Periodic Review Results: Continue |   |         |         |
| Objective: To evaluate the potential advantages of the use of sodium iodate following radioactive iodine administration in the treatment of Graves' hyperthyroidism. |  |                                   |   |         |         |

Technical Approach: The study was amended to study two groups. One group will receive the placebo and the other group will receive the drug. Neither the patients nor the physicians will know which capsule is being taken.

Progress: An IND for the placebo has been obtained; however, to date, the placebo has not been received.

# Detail Summary Sheet

|   |                               |                          |          |         |         |
|---|-------------------------------|--------------------------|----------|---------|---------|
| Date:   | 1 Nov 83                      | Proj No:                 | C-38-82  | Status: | Ongoing |
| TITLE:  |                               |                          |          |         |         |
| Autologous Bone Marrow Transplantation in Resistant Neoplasms: A Phase I Study              |                               |                          |          |         |         |
| Start Date  | 7 Jul 82                      | Est Comp Date:           | Jul 87   |         |         |
| Principal Investigator  | Facility                      |                          |          |         |         |
| Walter H. Harvey, D.O, MAJ, MC  | Brooke Army Medical Center    |                          |          |         |         |
| Dept/Sec  | Associate Investigators:      |                          |          |         |         |
| Department of Medicine/Hematology-Oncology  | Glenn M. Mills, M.D., MAJ, MC |                          |          |         |         |
| Key Words:  | James F. Boyd, M.D., LTC MC   |                          |          |         |         |
| Bone marrow transplantation   |                               |                          |          |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:    | Periodic Review Results: | Continue |         |         |
| Objectives: To develop a bone marrow transplantation program at Brooke Army Medical Center. |                               |                          |          |         |         |

To participate in research and clinical studies individually as well as part of the Southwest Oncology Group.

To establish a competent transplantation service for all eligible DOD patients for present clinical indications and future indications.

Technical Approach: Bone marrow stem cells will be obtained by multiple bone marrow aspirations under general or local anesthesia. The marrow will be prepared by accepted methods and either frozen for storage or returned to the patient after intensive chemotherapy.

Progress: All of the necessary equipment required for this study has not arrived. Also, no laboratory technicians has been assigned to learn the procedure of marrow preparation for storage.

It is anticipated that the study will start in the very near future.

# Detail Summary Sheet

|  |  |                          |                          |                               |         |
|--|--|--------------------------|--------------------------|-------------------------------|---------|
| Date:  | 1 Nov 83                                   | Proj No:                 | C-62-82                  | Status:                       | Ongoing |
| TITLE:   |  |                          |                          |                               |         |
| The Effect of Calcium Channel Blockers on Sickling and Blood Viscosity in Hgb SS Disease   |  |                          |                          |                               |         |
| Start Date   | 27 Sep 82                                  | Est Comp Date:           | Undetermined             |                               |         |
| Principal Investigator   | James F. Boyd, M.D., LTC, MC               |                          | Facility                 | Brooke Army Medical Center    |         |
| Dept/Sec   | Department of Medicine/Hematology-Oncology |                          | Associate Investigators: | Glenn M. Mills, M.D., MAJ, MC |         |
| Key Words:   | Hgb SS disease                             |                          | John J. Posch, Jr., DAC  |                               |         |
|  | Calcium channel blockers                   |                          | Barbara Reeb             |                               |         |
|  | Sickling                                   |                          |                          |                               |         |
|  | Blood viscosity                            |                          |                          |                               |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:                 | Periodic Review Results: |                          |                               |         |
| Objective: To study the <u>in vitro</u> effect of calcium channel blockers on sickling and on blood viscosity in Hgb SS disease. |  |                          |                          |                               |         |

Technical Approach: Blood from patients with hemoglobin SS disease will be drawn in heparinized tubes and a specified amount of a calcium channel blocker (either Verapamil or Nifedipine) will be added. The change in whole blood viscosity, as measured by Wells-Brookfield cone plate viscometer, will be determined and will be compared with the patient's own blood without added calcium channel blocker.

Progress: The initiation of this project has been significantly delayed due to the delay in ordering and delivery of the white blood viscometer. Within past week the viscometer has been delivered and has been set up. We are now prepared to begin standardization of the viscometer and within a month to six weeks plan to begin the sickle cell studies.

# Detail Summary Sheet

|   |          |                  |                                |                       |         |
|---|----------|------------------|--------------------------------|-----------------------|---------|
| Date:   | 1 Nov 83 | Proj No:         | C-63-82                        | Status:               | Ongoing |
| TITLE:  |          |                  |                                |                       |         |
| Evaluation of Catheter-Mounted Micromanometers vs External Fluid Transducers for Continuous Pressure Monitoring in the Coronary Care Unit |          |                  |                                |                       |         |
| Start Date  |          |                  | 27 Sep 82                      | Est Comp Date: Sep 84 |         |
| Principal Investigator  |          |                  | Facility                       |                       |         |
| William E. Craig, M.D., MAJ, MC   |          |                  | Brooke Army Medical Center     |                       |         |
| Dept/Sec  |          |                  | Associate Investigators:       |                       |         |
| Department of Medicine/Cardiology   |          |                  | Joseph P. Murgu, M.D., COL, MC |                       |         |
| Key Words:  |          |                  |                                |                       |         |
| Continuous pressure monitoring  |          |                  |                                |                       |         |
| Catheter-mounter micromanometers  |          |                  |                                |                       |         |
| Accumulative MEDCASE  |          | Est Accumulative |                                | Periodic              |         |
| Cost:   |          | OMA Cost:        |                                | Review Results:       |         |

Objectives: To evaluate the use of high fidelity catheter-mounted micromanometer transducers on flow-directed balloon-tipped right heart catheters in the Coronary Care Unit.

To determine whether the more accurate pressures obtained from the micromanometers are significantly different than those obtained from conventional fluid-filled transducer systems and whether or not these differences would change or improve the clinical management of patients requiring hemodynamic monitoring.

Technical Approach: This study is performed in patients in the Coronary Care Unit who require Swan-Ganz catheterization for clinical purposes. Rather than the standard catheter, a Swan-Ganz catheter which has been modified to contain a micromanometer pressure transduce is used. This catheter permits usual pressure monitoring techniques in addition to acquisition of hi-fidelity pulmonary artery pressures.

Progress: There have been no adverse effects or physical injuries sustained as a result of participation in the study. The data obtained thus far indicates that hi-fidelity pressure monitoring by means of catheter mounted micromanometer transducers significantly improves the quality and use of hemodynamic data obtained on patients in the Coronary Care Unit.

# Detail Summary Sheet

|  |                                    |                          |                                       |         |         |
|--|------------------------------------|--------------------------|---------------------------------------|---------|---------|
| Date:  | 1 Nov 83                           | Proj No:                 | C-66-82                               | Status: | Ongoing |
| TITLE:   |                                    |                          |                                       |         |         |
| Detection of Immune Complexes in Serum and Synovial Fluid of Patients with Rheumatic Diseases and Other Diseases Characterized by Circulating Immune Complexes |                                    |                          |                                       |         |         |
| Start Date   | 27 Sep 82                          | Est Comp Date: Sep 84    |                                       |         |         |
| Principal Investigator   |                                    |                          | Facility                              |         |         |
| Charles S. Via, M.D., MAJ, MC  |                                    |                          | Brooke Army Medical Center            |         |         |
| Dept/Sec   |                                    |                          | Associate Investigators:              |         |         |
| Department of Medicine/Rheumatology  |                                    |                          | Robert C. Allen, M.D., Ph.D., MAJ, MC |         |         |
| Key Words:   |                                    |                          |                                       |         |         |
| Immune Complexes   |                                    |                          |                                       |         |         |
| Rheumatic diseases   |                                    |                          |                                       |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: \$5,623 | Periodic Review Results: |                                       |         |         |
| Objectives: Study the effects of sera and synovial fluids containing immune complexes (IC's) on normal granulocyte function.                                   |                                    |                          |                                       |         |         |

Develop an assay for quantifying serum or synovial fluid IC activity based upon direct stimulation of granulocyte oxygenation activity, or inhibition of oxygenation response to a second stimulus. Correlate these findings with currently used clinical laboratory techniques for IC detection such as Clq binding.

Develop techniques for quantifying the autoantibody activities of serum or synovial fluid for antigens such as DNA, ribonucleoprotein, mitochondria, et cetera.

Measure the pre- and post-stimulation oxygenation activity of granulocytes (using microliter quantities of whole blood or synovial fluid aspirates) from patients with immune complex associated diseases.

Technical Approach: An assay for immune complexes using isolated PMNL's and another using whole blood has been developed and standardized. An assay for synovial fluid inflammatory activity and cellular function has been developed and standardization is in progress.

Progress: Serum from patients with SLE, RA, and other immune complex diseases will directly induce neutrophil chemiluminescence. In SLE, the amount of PMNL CL is directly related to other clinical and serological parameters of disease activity. Additionally, stimulation of PMNL by synthetic immune complexes or serum containing ICs inhibits the CL response to a subsequent challenge. This may contribute to the increased susceptibility to infection in these patients.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-67-82 Status: Ongoing

## TITLE:

Pathogenesis of Tissue Injury in Porphyria

|                        |  |                          |                            |
|------------------------|--|--------------------------|----------------------------|
| Start Date             | 27 Sep 82  | Est Comp Date:           | Sep 85                     |
| Principal Investigator | Charles W. Lewis, M.D., COL, MC                    | Facility                 | Brooke Army Medical Center |
| Dept/Sec               | Department of Medicine/Dermatology                 | Associate Investigators: | Deborah A. Spive, M.D.     |
| Key Words:             | <p>Porphyria<br/>Erythropoietin<br/>Porphyrins</p> |                          |                            |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To investigate the pathophysiology by which circulating porphyrins produce hyperviscosity states and to determine the extent of tissue injury produced.

To determine the effects of ultraviolet rays (UVA, UVB, Soret Band) on the deposition of porphyrins in the skin.

To evaluate the role of erythropoietin as the primary stimulus of the bone marrow's overproduction of porphyrin precursors/heme and to determine the effect of suppressing this stimulus.

To examine immunologic parameters caused by fixed porphyrins, i.e., IgG deposition and complement activation by porphyrins.

Technical Approach: Red cell exchanges were performed with both the Haemonetics PEX and the Fenwal Centrifuge II in the Medical Intensive Care Unit with continuous cardiac monitoring, using washed autologous units and random blood units to maintain hematocrits above 35%. Donor units were matched for all major blood group antigens and underwent same washing procedure.

Induction phase consisted of 1000 ml RBC exchanges every three to seven days until complete remission of clinical symptoms and normal porphyrin levels were obtained (3 to 10 exchanges). Subsequent exchanges for maintenance were performed at increasingly longer intervals. Multiple parameters were monitored pre- and post-exchange.

Progress: Ten patients (with AIP, EPP, PCT, HC or variegate porphyria) have obtained complete clinical and chemical remissions by combining plasmapheresis with red cell exchange transfusions using autologous washed cells (yielding neocytes) and/or donor neocytes for periods of 2-12 months.

# Detail Summary Sheet

|  |          |           |                              |                |           |
|--|----------|-----------|------------------------------|----------------|-----------|
| Date:  | 1 Nov 83 | Proj No:  | C-2-83                       | Status:        | Completed |
| TITLE:   |          |           |                              |                |           |
| Effect of Intravenous Administration of Didronel (Etidronate Disodium) on Serum Calcium in Patients with Hypercalcemia Due to Malignant Disease. |          |           |                              |                |           |
| Start Date   |          | 10 Nov 82 |                              | Est Comp Date: |           |
| Principal Investigator   |          |           | Facility                     |                |           |
| Thomas J. Taylor, M.D., MAJ, MC  |          |           | Brooke Army Medical Center   |                |           |
| Dept/Sec   |          |           | Associate Investigators:     |                |           |
| Department of Medicine/Endocrinology   |          |           | James F. Boyd, M.D., LTC, MC |                |           |
| Key Words:   |          |           | Marc Troxell, M.D., CPT, MC  |                |           |
| Hypercalcemia  |          |           |                              |                |           |
| Etidronate disodium  |          |           |                              |                |           |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To examine the effectiveness of intravenous infusion of etidronate disodium in lowering the serum calcium levels in patients experiencing hypercalcemia due to their malignant disease.

To evaluate the tolerance of intravenous infusion of etidronate disodium in these patients.

Technical Approach: Patients admitted to the study received 7.5 mg/kg didronel 1-3 times per day for 1-3 days. No other medications to control serum calcium were given. Patient's response to the infusion was evaluated on days 1, 2, 3, 4, 5, 7, and 10.

Progress: Twenty patients from three participating medical centers were entered on the study. Since results were encouraging, it was decided to delete group 2, i.e. those receiving didronel 2 times a day for 1-3 days. The results of this study are reported under protocol number C-29-83.



# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-3-83 Status: Terminated

## TITLE:

A Pilot Double-Blind Evaluation of BW942C and Placebo in Acute Nonspecific Diarrhea

|   |          |                            |
|---|----------|----------------------------|
| Start Date                              | 6 Jan 83 | Est Comp Date:             |
| Principal Investigator                  |          | Facility                   |
| Rolando Longoria, M.D., CPT, MC         |          | Brooke Army Medical Center |
| Dept, Sec                               |          | Associate Investigators:   |
| Department of Medicine/Gastroenterology |          |                            |
| Key Words:                              |          |                            |
| Nonspecific diarrhea                    |          |                            |

|                      |                  |                 |
|----------------------|------------------|-----------------|
| Accumulative MEDCASE | Est Accumulative | Periodic        |
| Cost:                | OMA Cost:        | Review Results: |

Objectives: To assess the safety and efficacy of oral doses of BW942C in patients with acute nonspecific diarrhea.

To determine a dose and dosing interval to be employed in subsequent Phase II antidiarrheal trials.

Technical Approach: None.

Progress: This study was not started prior to the PCS of the principal investigator. Other members of the Gastroenterology staff were not interested in completing the study.

# Detail Summary Sheet

|  |                                    |                          |  |         |         |
|--|------------------------------------|--------------------------|--|---------|---------|
| Date:  | 1 Nov 83                           | Proj No:                 | C-7-83   | Status: | Ongoing |
| TITLE:   |                                    |                          |  |         |         |
| The Clinical Effects of Four Different Topical Nitrate Preparations in Patients with Stable Angina Pectoris  |                                    |                          |  |         |         |
| Start Date   | 10 Nov 82                          | Est Comp Date:           | Dec 84   |         |         |
| Principal Investigator (vice Moody)  | Steven R. Bailey, M.D., MAJ, MC    | Facility                 | Brooke Army Medical Center                         |         |         |
| Dept/Sec   | Department of Medicine/Cardiology  | Associate Investigators: | Stuart Damore, M.D., MAJ, MC                       |         |         |
| Key Words:   | Angina pectoris<br>Topical nitrate |                          | Tinker Murray, DAC<br>Bernard J. Rubal, Ph.D., DAC |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:         | Periodic Review Results: |  |         |         |
| Objective: To evaluate the clinical effectiveness of Nitrol, Transderm-Nitro, Nitro-Dur, and Nitro-Disc in the medical management of patients with stable angina pectoris. |                                    |                          |  |         |         |

Technical Approach: This study was recently assumed by MAJ Bailey. An effort is being made to acquire the materials required to initiate the study.

Progress: None.

# Detail Summary Sheet

|  |           |                                      |        |         |           |
|--|-----------|--------------------------------------|--------|---------|-----------|
| Date:  | 12 Dec 83 | Proj No:                             | C-9-83 | Status: | Completed |
| TITLE:   |           |                                      |        |         |           |
| PZA-ase Content of <u>Mycobacterium Tuberculosis</u> . |           |                                      |        |         |           |
| Start Date   | 6 Jan 83  | Est Comp Date:                       |        |         |           |
| Principal Investigator                                 |           | Facility                             |        |         |           |
| John L. Carpenter, M.D., COL, MC                       |           | Brooke Army Medical Center           |        |         |           |
| Dept/Sec   |           | Associate Investigators:             |        |         |           |
| Department of Medicine/Infectious Disease              |           | Charles E. Davis, Jr., M.D., CPT, MC |        |         |           |
| Key Words:   |           | Eugene T. Etzkorn, M.D., MAJ, MC     |        |         |           |
| PZA-ase  |           | S. Vern Juchau, LTC, MC              |        |         |           |
| <u>Mycobacterium tuberculosis</u>                      |           |                                      |        |         |           |

|   |                            |                          |
|---|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objective: To determine the incidence of PZA-ase production and capreomycin sensitivity of <u>Mycobacterium tuberculosis</u> isolates in South Texas and in a large Army referral hospital. |                            |                          |

Technical Approach: All Mycobacterium tuberculosis isolates isolated in the Brooke Army Medical Center (BAMC) Mycobacteriology Laboratory and in the San Antonio State Chest Hospital Laboratory thru 30 Jun 83 were utilized. The isolates were identified by standard techniques. All isolates from the San Antonio State Chest Hospital had anti-tuberculosis sensitivity testing performed by a standard agar diffusion technique, and all BAMC isolates were tested by standard disk diffusion technique. Capreomycin sensitivities were performed by the State Chest Hospital. Drugs tested included INH, ethambutol, rifampin, capreomycin, and streptomycin. Pyrazinamide sensitivities were determined at the CDC. PZA-ase determinations were performed by the standard Wayne method at BAMC.

Progress: One hundred and sixty six isolates of M. tuberculosis were tested using this method. Seven of these isolates were found to be PZA-ase negative (4.2%).

The negative isolates plus some of the other isolates were sent to CDC for confirmation, however, during the transferring process, the majority of the isolates became contaminated with Mycobacterium Fortuitum.

Due to the lack of confirmation of our data, plus the fact that the CDC has denied a more simple minimal inhibitory concentration determination which is less time consuming, we have discontinued this project.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-15-83 Status: Ongoing

## TITLE:

The Treatment of Cellulitis

|                        |   |                          |                            |
|------------------------|---|--------------------------|----------------------------|
| Start Date             | 3 Mar 83                                  | Est Comp Date:           | Aug 84                     |
| Principal Investigator | C. Kenneth McAllister, M.D., LTC, MC      | Facility                 | Brooke Army Medical Center |
| Dept/Sec               | Department of Medicine/Infectious Disease | Associate Investigators: |                            |
| Key Words:             | Cellulitis                                |                          |                            |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To compare the response of outpatients with cellulitis who are randomized to receive either erythromycin or dicloxicillin. |                            |                          |

To compare the response of inpatients with cellulitis who are randomized to receive either erythromycin or nafcillin.

Technical Approach: Patients are randomized to receive one of the antibiotics, either by vein initially (if hospitalized) or by mouth if they are to be followed as outpatients, for a total of 10 days of treatment. Follow-up evaluations will be done on the 3rd, 6th, 9th, and 14th day after treatment is begun. The skin infection will be circled with a colored pencil initially and measured at each evaluation.

Progress: This study began 1 August and is currently progressing well. Nine patients have been entered.

# Detail Summary Sheet

|   |                            |                          |                                    |         |         |
|---|----------------------------|--------------------------|------------------------------------|---------|---------|
| Date:   | 1 Nov 83                   | Proj No:                 | C-16-83                            | Status: | Ongoing |
| TITLE:  |                            |                          |                                    |         |         |
| Prospective Evaluation of Clinical, X-ray, Histologic Scintigraphic and Microbiologic Characteristics of Diabetic Feet  |                            |                          |                                    |         |         |
| Start Date  | 3 Mar 83                   | Est Comp Date:           | Mar 86                             |         |         |
| Principal Investigator  |                            |                          | Facility                           |         |         |
| C. Kenneth McAllister, M.D., LTC, MC  |                            |                          | Erooke Army Medical Center         |         |         |
| Dept/Sec  |                            |                          | Associate Investigators:           |         |         |
| Department of Medicine/Infectious Disease   |                            |                          | John B. L. McClain, M.D., MAJ, MC, |         |         |
| Key Words:  |                            |                          | Chief, Infectious Disease Service  |         |         |
| Diabetic feet   |                            |                          | Walter Reed Army Medical Center    |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: |                                    |         |         |
| Objective: To correlate specific x-ray, scintigraphic, clinical, and microbiologic characteristics with each other and with the histology of the diseased diabetic foot so clinicians may better manage their patients. |                            |                          |                                    |         |         |

Technical Approach: The histologic appearance of osteomyelitis in the amputated diabetic foot will be studied. The histologic appearance will be compared with clinical and radiographic findings to determine the specificity of diagnosing osteomyelitis.

Progress: No specimens have been added to this study from BAMC.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-21-83 Status: Ongoing

## TITLE:

An Investigation of Immunological Reaction to Human Serum Albumin

|                        |   |                          |   |
|------------------------|---|--------------------------|---|
| Start Date             | 3 Mar 83  | Est Comp Date:           | Mar 85  |
| Principal Investigator | Daniel A. Ramirez, M.D., LTC, MC  | Facility                 | Brooke Army Medical Center                                    |
| Dept/Sec               | Department of Medicine/Allergy-Immunology                                   | Associate Investigators: | H. S. Nelson, M.D., COL, MC<br>Fitzsimons Army Medical Center |
| Key Words:             | Allergy extracts<br>IgE antibodies<br>IgG antibodies<br>Human serum albumin |                          |   |
| Accumulative MEDCASE   | Est Accumulative  | Periodic                 |   |
| Cost:                  | OMA Cost:   | Review Results:          |   |

Objective: To determine whether allergy patients receiving injections of allergy extracts containing human serum albumin develop evidence of IgE or IgG antibodies directed towards human serum albumin.

Technical Approach: Patients on immunotherapy for one year or greater will be entered. These patients will be skin tested with 0.03% HSA containing diluent with a histamine and saline control. One out of ten patients will have blood drawn for specific IgE/IgG which will be processed at FAMC.

Progress: Only one patient has been entered. Patient was negative on skin testing, and no adverse effect was noted from the skin testing.

# Detail Summary Sheet

|   |                                  |                |         |         |         |
|---|----------------------------------|----------------|---------|---------|---------|
| Date:   | 1 Nov 83                         | Proj No:       | C-22-83 | Status: | Ongoing |
| TITLE:  |                                  |                |         |         |         |
| The Sputum Gram Stain and Culture in the Diagnosis of Adult Community-Acquired Pneumonias |                                  |                |         |         |         |
| Start Date  | 3 Mar 83                         | Est Comp Date: | Feb 85  |         |         |
| Principal Investigator  | Facility                         |                |         |         |         |
| Lawrence Pupa, M.D., CPT, MC  | Brooke Army Medical Center       |                |         |         |         |
| Dept/Sec  | Associate Investigators:         |                |         |         |         |
| Department of Medicine/Chief Resident   | John L. Carpenter, M.D., COL, MC |                |         |         |         |
| Key Words:  |                                  |                |         |         |         |
| Community-acquired pneumonia  |                                  |                |         |         |         |

|  |                  |                 |
|--|------------------|-----------------|
| Accumulative MEDCASE   | Est Accumulative | Periodic        |
| Cost:  | OMA Cost: \$861  | Review Results: |
| Objectives: To conduct a prospective evaluation of the usefulness of the sputum gram stain and subsequent sputum culture results in the diagnosis and management of community-acquired pneumonia in the adult. |                  |                 |

To document the relative incidences of various organisms in causing community-acquired pneumonias.

Technical Approach: Sputums obtained during routine evaluation of patients with community-acquired pneumonia have been reviewed by both housestaff and principal investigators. Comparisons were made to directed and nondirected cultures and effect of therapeutic decision analyzed.

Progress: Forty-two patients have been studied. 33% of housestaff readings were inadequate. Housestaff uses gram stains 95% time to direct monotherapy. Inaccurately interpreted gram stains led to slower resolution of symptoms but no increase in morbidity or mortality.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-23-83 Status: Terminated

## TITLE:

A Comparison of Pseudomonic Acid with Placebo in Patients with Skin Infections

Start Date 3 Mar 83 Est Comp Date:

Principal Investigator Facility

Eric W. Kraus, M.D., LTC, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Medicine/Dermatology

## Key Words:

Pseudomonic acid

Skin infections

Accumulative MEDCASE Est Accumulative Periodic

Cost: OMA Cost: Review Results:

Objective: To compare the safety and efficacy of pseudomonic acid with placebo in patients with skin infections.

Technical Approach: Patients with culture proven secondarily infected cutaneous lesions (i.e., abrasions, burns, etc.) were treated on a double-blind protocol comparing pseudomonic acid to placebo. Eight patients entered and completed the study.

Progress: One patient dropped out of the trial because of non-response and was treated with known appropriate therapy. Although some patients complained of irritation, there were no significant side effects or injuries from this treatment.

The study was terminated at the request of the drug company.



# Detail Summary Sheet

|   |                                |                 |         |         |         |
|---|--------------------------------|-----------------|---------|---------|---------|
| Date:   | 1 Nov 83                       | Proj No:        | C-26-83 | Status: | Ongoing |
| TITLE:  |                                |                 |         |         |         |
| A Study of the Transmission of the Arterial Pulse Pressure Wave Form in the Descending Aorta of Man                 |                                |                 |         |         |         |
| Start Date  | 16 Mar 83                      | Est Comp Date:  | Jun 84  |         |         |
| Principal Investigator  | Facility                       |                 |         |         |         |
| Ricky Latham, M.D., CPT, MC   | Brooke Army Medical Center     |                 |         |         |         |
| Dept/Sec  | Associate Investigators:       |                 |         |         |         |
| Department of Medicine/Cardiology   | Joseph P. Murgu, M.D., COL, MC |                 |         |         |         |
| Key Words:  | Nico Westerhof, M.D.           |                 |         |         |         |
| Pulse wave velocity   |                                |                 |         |         |         |
| Pressure wave form  |                                |                 |         |         |         |
| Wave reflection   |                                |                 |         |         |         |
| Accumulative MEDCASE  | Est Accumulative               | Periodic        |         |         |         |
| Cost:   | OMA Cost:                      | Review Results: |         |         |         |
| Objectives: To examine the changes in the arterial pulse pressure wave form throughout the descending aorta of man. |                                |                 |         |         |         |

To determine the pulse wave velocity at various sites in the descending aorta.

To determine the significance of wave reflection sites in the descending aorta.

Technical Approach: Specially designed 6-sensor catheter with micromanometers mounted 10 cm. apart on a 8F catheter are used. Placement of this catheter in the aorta to femoral artery permits 8 simultaneous pressure measurements in the aorta-iliac artery.

Progress: Normal subject group almost complete. Thus far nine patients have been studied. Data analysis will begin shortly.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-27-83 Status: Ongoing  
 TITLE:

A Multi-Site Study of the Effects of Intravenous Didronel (Etidronate Disodium) on Hypercalcemia Due to Malignant Disease or Primary Hyperparathyroidism

|   |  |
|---|--|
| Start Date 16 Mar 83                                      | Est Comp Date: Mar 84                                    |
| Principal Investigator<br>Thomas J. Taylor, M.D., MAJ, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Endocrinology          | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Didronel<br>Hyperparathyroidism             |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To compare the effectiveness and tolerance of saline plus intravenous infusion of Didronel with saline alone in lowering the serum calcium level in patients experiencing hypercalcemia due to malignant disease or primary hyperparathyroidism.

To evaluate the effectiveness of oral Didronel at maintaining serum calcium in the normal range.

Technical Approach: Patients are randomly assigned to receive one of two treatment programs. Treatment program #1 is standard therapy which consists of giving fluids by vein to increase urine output and calcium excretion. Treatment program #2 consists of giving fluids plus Didronel by vein for three days. If at the end of seven days serum calcium levels of patients assigned to treatment program #2 have returned to normal, they will be given either Didronel by mouth or a placebo for a period of three months.

Progress: Only one patient has been entered on this study. No reportable data are available.

# Detail Summary Sheet

|   |                            |                    |
|---|----------------------------|--------------------|
| Date: 1 Nov 83  | Proj No: C-28-83           | Status: Terminated |
| TITLE: Multicenter, Double-Blind, Randomized, Parallel Comparison of Two Different Dosage Regimens of Naproxen Sodium in Patients with Bone Pain Due to Metastatic Cancer |                            |                    |
| Start Date 19 Apr 83  | Est Comp Date:             |                    |
| Principal Investigator  | Facility                   |                    |
| James F. Boyd, M.D., LTC, MC  | Brooke Army Medical Center |                    |
| Dept/Sec  | Associate Investigators:   |                    |
| Department of Medicine/Hematology-Oncology  | Greg Friess, M.D., CPT, MC |                    |
| Key Words:  |                            |                    |

|  |                  |                 |
|--|------------------|-----------------|
| Accumulative MEDCASE   | Est Accumulative | Periodic        |
| Cost:  | OMA Cost:        | Review Results: |
| Objective: To compare the relative efficacy and safety of a higher total daily dose of naproxen sodium to a lower total daily dose in patients with moderate to severe, persistent bone pain due to metastatic cancer. |                  |                 |

Technical Approach: None.

Progress: After approval and registration of the protocol, the principal investigators decided not to do the study.

# Detail Summary Sheet

Date: 1 Nov 83 Proj No: C-29-83 Status: Ongoing

## TITLE:

The Effect of Intravenous Administration of Didronel (Etidronate Disodium) on Serum Calcium in Patients with Hypercalcemia Due to Malignant Disease

Start Date 19 Apr 83 Est Comp Date: Apr 84

Principal Investigator

Facility

Thomas J. Taylor, M.D., MAJ, MC

Brooke Army Medical Center

Dept/Sec

Associate Investigators:

Department of Medicine/Endocrinology

James F. Boyd, M.D., LTC, MC

Key Words:

Hypercalcemia

Didronel

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost:

Review Results:

Objectives: To examine the effectiveness of intravenous infusion of etidronate disodium in lowering the serum calcium level in patients experiencing hypercalcemia due to malignant disease.

To evaluate further the tolerance of intravenous infusion of etidronate disodium in these patients.

Technical Approach: This is phase 2 of the study reported under project number C-2-83. In the present study, etidronate disodium, 7.5 mg/kg, was infused over a 2 hour period for 1-3 consecutive days in a limited number of patients as treatment for hypercalcemia. All patients were hydrated and had a persistent hypercalcemia for 48 hours before entering the study.

In approximately 60% of patients considered for the study, serum calcium normalized as a result of hydration alone and therefore were excluded from the study. Patients with hypercalcemia due to any type of malignant disease were admitted to the study. Hypercalcemia which resulted from primary hyperparathyroidism was not studied.

Progress: Most patients had a prompt response to IV etidronate disodium with their serum calcium entering the normal range 2-6 days after the initiation of therapy. When all patients are considered, the mean time to normalization was 4-5 days. A statistically significant ( $p < .05$ ) drop in mean serum calcium from the mean pretreatment value was seen at day 4. Of 11 responding patients, 8 patients had normalization of their serum calcium in 2-4 days. Only one of the responding patients subsequently failed during the 10-day follow-up period. This patient was a 63-year-old male with multiple myeloma. Thus far in this multi-center study, 13 patients have been treated - 5 with breast cancer, 5 with squamous cell cancer of the lung or neck, 2 with multiple myeloma, and 1 with colon cancer. Good response has been noted in all disease categories.

Detail Summary Sheet

|  |                            |                          |         |         |         |
|--|----------------------------|--------------------------|---------|---------|---------|
| Date:  | 2 Nov 83                   | Proj No:                 | C-33-83 | Status: | Ongoing |
| TITLE:   |                            |                          |         |         |         |
| Nifedipine in Methacholine-Induced Bronchospasm  |                            |                          |         |         |         |
| Start Date   | 19 Apr 83                  | Est Comp Date:           | Apr 84  |         |         |
| Principal Investigator   | Facility                   |                          |         |         |         |
| Joseph I. Matthews, M.D., COL, MC  | Brooke Army Medical Center |                          |         |         |         |
| Dept/Sec   | Associate Investigators:   |                          |         |         |         |
| Department of Medicine/Pulmonary Disease   |                            |                          |         |         |         |
| Key Words:   |                            |                          |         |         |         |
| Bronchospasm   |                            |                          |         |         |         |
| Nifedipine   |                            |                          |         |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |         |         |         |
| Objective: To determine if nifedipine can alter bronchial reactivity in patients with methacholine-induced bronchospasm. |                            |                          |         |         |         |

**Technical Approach:** The protocol as originally written called for the use of a placebo. However, since we were unable to obtain the placebo, the study was revised, and approval was obtained to conduct the study without the use of placebo.

Eight patients were challenged with methacholine as per the standard operating procedure for methacholine challenge test. Baseline pulmonary function studies were done. A second methacholine challenge was performed 72 hours after the initial challenge. Each patient received 20 mg of nifedipine orally 90 to 180 minutes prior to the second study.

**Progress:** It was concluded from the amended study that nifedipine does not alter methacholine-induced and, by inference, cholinergically-induced bronchial reactivity.

We have now received the IND for obtaining the nifedipine placebo. Therefore, the study will now be conducted as originally approved.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-37-83 Status: Ongoing

## TITLE:

Short-Course Chemotherapy of Pulmonary Tuberculosis

|                        |   |                          |                            |
|------------------------|---|--------------------------|----------------------------|
| Start Date             | 6 May 83                                  | Est Comp Date:           | Jun 85                     |
| Principal Investigator | Eugene T. Etzkorn, M.D., MAJ, MC          | Facility                 | Brooke Army Medical Center |
| Dept/Sec               | Department of Medicine/Infectious Disease | Associate Investigators: |                            |
| Key Words:             | Pulmonary tuberculosis<br>Chemotherapy    |                          |                            |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To compare the efficacy, toxicity, and acceptability of a 6-month regimen of isoniazid and rifampin, supplemented by pyrazinamide for the first two months, with a control regimen of 9 months of isoniazid-rifampin in patients with pulmonary tuberculosis.

To determine the acceptability of supervised twice-weekly therapy for patients who fail to adhere to the self-administered daily regimens.

Technical Approach: No patients were entered into the study.

Progress: None due to lack of patients eligible for the study.

# Detail Summary Sheet

|   |                                   |                          |                            |         |         |
|---|-----------------------------------|--------------------------|----------------------------|---------|---------|
| Date:   | 2 Nov 83                          | Proj No:                 | C-38-83                    | Status: | Ongoing |
| TITLE:  |                                   |                          |                            |         |         |
| Echocardiographic Evaluation of Cardiac Performance and Mitral Valve Function Under +G <sub>z</sub> Stress  |                                   |                          |                            |         |         |
| Start Date  | 6 May 83                          | Est Comp Date: Oct 84    |                            |         |         |
| Principal Investigator  | Paul V. Celio, M.D., CPT, USAF MC |                          | Facility                   |         |         |
| Dept/Sec  | Department of Medicine/Cardiology |                          | Brooke Army Medical Center |         |         |
| Key Words:  | G-stress<br>Echocardiography      |                          | Associate Investigators:   |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:        | Periodic Review Results: |                            |         |         |
| Objectives: To examine the alterations in cardiac performance and mitral function during increased gravitational loading induced by acceleration in the human centrifuge. |                                   |                          |                            |         |         |

Technical Approach: Several attempts have been made to install ultrasound equipment in the human centrifuge. These attempts have failed. The U.S. Air Force is currently seeking contracts from vendors for equipment installation.

Progress: No subjects have been entered due to technical problems.

# Detail Summary Sheet

|   |  |                       |  |         |         |
|---|--|-----------------------|--|---------|---------|
| Date:   | 2 Nov 83                                 | Proj No:              | C-39-83                                | Status: | Ongoing |
| TITLE:  |  |                       |  |         |         |
| Mechanisms of Exercise Limitation in Patients with Obstructive Lung Disease |  |                       |  |         |         |
| Start Date  | 6 May 83                                 | Est Comp Date: May 85 |  |         |         |
| Principal Investigator  | Joseph I. Matthews, M.D., Colonel, MC    |                       | Facility                               |         |         |
| Dept/Sec  | Department of Medicine/Pulmonary Disease |                       | Brooke Army Medical Center             |         |         |
| Key Words:  | Obstructive lung disease                 |                       | Associate Investigators:               |         |         |
|   |  |                       | Cornelius J.P. Sullivan, M.D., MAJ, MC |         |         |
|   |  |                       | Bruce A. Bush, M.D , CPT, MC           |         |         |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the mechanism by which patients with obstructive lung disease are limited in their ability to perform exercise.

To examine ventilatory patterns in patients with obstructive lung disease during different types of exercise.

To determine if there is a specific level of lung function at which point pulmonary rather than cardiac or conditioning factors limit the ability to perform exercise.

To determine if age-matched controlled patients with reasonably normal lung function develop abnormal ventilatory patterns during similar modes of exercise.

Technical Approach: Patients with an FEV<sub>1</sub> of less than 75% of predicted which is due to obstructive lung disease will be studied. A cycle ergometer will be used. Prior to the study, all patients will have complete pulmonary function studies to include FVC, FEV<sub>1</sub>, FEV<sub>1</sub>%, MMEF, RV, TLC, DL<sub>CO</sub>, and MVV measured on a CPI 5000 Pulmonary Function Laboratory. Spirometry will also be done pre- and post-bronchodilators. Three separate tests will be done at each setting.

Progress: The "System 2000 Medical Graphics Corporation's Cardio-Pulmonary Exercise Lab System" has not been received. Therefore, no patients have been entered on the study.



# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-42-83 Status: Ongoing

## TITLE:

Electrolyte Abnormalities and Delirium Tremens

|                        |                                       |                          |                                 |
|------------------------|---------------------------------------|--------------------------|---------------------------------|
| Start Date             | 6 May 83                              | Est Comp Date:           | May 84                          |
| Principal Investigator | Lawrence Pupa, M.D., CPT, MC          | Facility                 | Brooke Army Medical Center      |
| Dept/Sec               | Department of Medicine/Chief Resident | Associate Investigators: | Melvin L. Butler, M.D., COL, MC |
| Key Words:             | Delitrium tremens                     |                          |                                 |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: Prospective evaluation of electrolyte abnormalities as predictors for the development of delirium tremens.

Technical Approach: All patients older than 18 years of age admitted to the BAMC medical wards with the diagnosis of alcohol withdrawal, made either before or after admission will be entered into the study. The daily SMA-6 for the first five hospital days or until discharge, whichever comes first, will be recorded. Correlation of the daily serum electrolytes and magnesium and development of DT's will be made prospectively.

Progress: Twenty-two patients have been studied. Neither  $K^+$  nor  $Mg^{++}$ , to date, appears to correlate with DT's, in contradistinction to some previous reports.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-51-83 Status: Ongoing

## TITLE:

Use of Isotretinoin in Prevention of Basal Cell Carcinoma

|   |  |
|---|--|
| Start Date 16 Jun 83  | Est Comp Date: Jun 88                  |
| Principal Investigator<br>Stuart J. Salasche, M.D., COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department Medicine/Dermatology                 | Associate Investigators:               |
| Key Words:<br>Isotretinoin<br>Basal cell carcinoma          |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To evaluate the effectiveness of low dosage levels of isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population.

To examine possible side effects associated with long term administration of low doses of isotretinoin.

Technical Approach: At this point the study has not actually begun. We are in a preparatory phase and have accomplished: 1) identification of a potential pool of about 250 patients; 2) Hired a nurse practitioner to be study coordinator; and 3) executed interagency agreement with NIH/NCI.

Progress: None.

# Detail Summary Sheet

|   |                                       |                |         |         |         |
|---|---------------------------------------|----------------|---------|---------|---------|
| Date:   | 2 Nov 83                              | Proj No:       | C-55-83 | Status: | Ongoing |
| TITLE:  |                                       |                |         |         |         |
| Efficacy of Weekly Pulse Methotrexate in the Treatment of Rheumatoid Arthritis: A Double Blind Crossover Study. |                                       |                |         |         |         |
| Start Date  | 8 Jul 83                              | Est Comp Date: | Jul 84  |         |         |
| Principal Investigator  | Facility                              |                |         |         |         |
| Charles S. Via, M.D., MAJ, MC   | Brooke Army Medical Center            |                |         |         |         |
| Dept/Sec  | Associate Investigators:              |                |         |         |         |
| Department of Medicine/Rheumatology   | Robert C. Allen, M.D., Ph.D., MAJ, MC |                |         |         |         |
| Key Words:  |                                       |                |         |         |         |
| Rheumatoid arthritis  |                                       |                |         |         |         |
| Methotrexate  |                                       |                |         |         |         |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To evaluate the effectiveness of weekly pulse methotrexate therapy to control the activity of rheumatoid arthritis by subjective and objective criteria by means of a 27-week double blind, crossover study against placebo in patients with active rheumatoid arthritis who have failed therapy with gold salt and D-penicillamine.

To evaluate the potential long-term weekly pulse methotrexate therapy to halt or decrease the progression of destructive changes of the articular cartilage and periarticular bone by means of sequential x-ray evaluation.

Technical Approach: During phase I of the study, patients will receive either IM methotrexate or placebo for 13 weeks. At the end of this period of time, they will receive whichever one they did not receive for an additional 13 weeks. If they respond to methotrexate, they will be continued on the most appropriate dose to control their arthritis (phase 2). Patients who continue on methotrexate will also be evaluated for potential injury to the liver (phase 3).

Progress: Five patients have been entered on the study. However, since they are still in the 1st arm of the study, no conclusions are available.

# Detail Summary Sheet

Date: Proj No: C-60-83 Status: Ongoing

TITLE:

Nifedipine in Patients with Recurrent Episodes of Bronchospasm.

|                        |  |                          |   |
|------------------------|--|--------------------------|---|
| Start Date             | 10 Aug 83                                | Est Comp Date:           | Aug 84                                    |
| Principal Investigator | Joseph I. Matthews, M.D., LTC, MC        | Facility                 | Brooke Army Medical Center                |
| Dept/Sec               | Department of Medicine/Pulmonary Disease | Associate Investigators: | Cornelius J. P. Sullivan, M.D.<br>MAJ, MC |
| Key Words:             | Nifedipine<br>Asthma<br>Bronchospasm     |                          |   |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine if nifedipine can alter clinical episodes of bronchospasm in patients with asthma, or allow patients with asthma to be maintained symptom-free on a lower dosage of medication.

Technical Approach: Fifteen to twenty asthmatic patients who are currently stable but require either toxic doses of medication or have frequent episodes of broncho-constriction manifested by episodic coughing, episodic wheezing, or episodic shortness of breath will be studied in a double-blind randomized crossover design. Patients will receive either nifedipine, 10 mg, or placebo. Initially one 10 mg capsule will be given orally after which heart rate and blood pressure will be monitored at 15-minute intervals for one hour. If no significant adverse effects are experienced during the first hour, the patient will be given another 10 mg nifedipine capsule and, once again, heart rate and blood pressure will be monitored. For patients able to tolerate the second 10 mg capsule without adverse effects, the dosage of nifedipine (or placebo) will be fixed at 2 capsules, whereas for patients who tolerated one 10 mg capsule but experienced adverse effects following administration of the second 10 mg capsule, the dosage will be fixed at 10 mg.

Progress: This is a new study. No patients have been entered.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-66-83 Status: Ongoing

## TITLE:

Epidemiological, Clinical and Therapeutic Investigations into Haemophilus ducreyi in American Troops in Korea

|   |  |
|---|--|
| Start Date 18 Aug 83                                    | Est Comp Date: Oct 84  |
| Principal Investigator<br>John Carpenter, M.D., COL, MC | Facility<br>Brooke Army Medical Center   |
| Dept/Sec<br>Department of Medicine/Office of Chief      | Associate Investigators:<br>Michael A. Sauri, M.D., MAJ, MC<br>Patricia Lillis, M.D., CPT, MC<br>Nancy DeSilva, M.D., MAJ, MC<br>Edward Shumski, M.D., LTC, MC |
| Key Words:<br><u>Haemophilus ducreyi</u>                |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: A demographic and clinical study of haemophilus ducreyi infections in American troops stationed in Korea will be undertaken.

There will be a double-blind, controlled study comparing the efficacy of drug therapy with short courses with erythromycin, septra, doxycycline, minocycline or the investigational drug, cefoxitin.

An epidemiological, clinical and microbiological/histopathological study of asymptomatic Korean contacts will be attempted.

Technical Approach: Sixty patients will be randomly assigned to one of five treatment programs. The criteria for selection will be based on the clinical picture of a venereal lesion manifested by the presence of skin ulceration, localized in the genital area of an exposed individual, which is associated with a negative dark field, VDRL and Zancck smear.

Ulcers will be cultured on enriched GC agar plates. Specimens will be sent to the area Laboratory at Brooke Army Medical Center for comparison with the various strains available.

Progress: No specimens have been received.

# Detail Summary Sheet

01

Date: 2 Nov 83 Proj No: C-67-83 Status: Ongoing

## TITLE:

AdOAP-High Dose Ara-C in Adult Acute Nonlymphocytic Leukemia (ANLL)

|                        |  |                          |                            |
|------------------------|--|--------------------------|----------------------------|
| Start Date             | 9 Sep 83                                   | Est Comp Date:           | Unknown                    |
| Principal Investigator | James F. Boyd, M.D., LTC, MC               | Facility                 | Brooke Army Medical Center |
| Dept/Sec               | Department of Medicine/Hematology-Oncology | Associate Investigators: |                            |
| Key Words:             | Acute Nonlymphocytic Leukemia              |                          |                            |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To determine whether early intensification therapy with high dose Cytosine arabinoside (Ara-C) will improve long term disease-free survival. |                            |                          |

To assess toxicity of high dose Ara-C used in conjunction with AdOAP induction therapy.

To determine whether maintenance therapy with low dose subcutaneous Ara-C will improve disease-free survival.

To determine the effect of high dose Ara-C intensification therapy on the incidence of CNS relapse.

Technical Approach: All patients over age 15 with a new diagnosis of acute leukemia who have not been previously treated are eligible for this study. Therapy will follow the schema outlined in the study protocol.

Progress: This is a new pilot study. If it proves to be effective, it will be submitted to the Southwest Oncology Group for consideration for further study.

# Detail Summary Sheet

|  |                                 |                 |         |         |         |
|--|---------------------------------|-----------------|---------|---------|---------|
| Date:  | 2 Nov 83                        | Proj No:        | C-70-83 | Status: | Ongoing |
| TITLE:   |                                 |                 |         |         |         |
| The Study of the Safety and Efficacy of Nizatidine as an H <sub>2</sub> Antagonist in Patients with Duodenal Ulcer Disease |                                 |                 |         |         |         |
| Start Date   | 9 Sep 83                        | Est Comp Date:  | Mar 84  |         |         |
| Principal Investigator   | Facility                        |                 |         |         |         |
| Fred Goldner, M.D., LTC, MC  | Brooke Army Medical Center      |                 |         |         |         |
| Dept/Sec   | Associate Investigators:        |                 |         |         |         |
| Department of Medicine/Gastroenterology  | Christopher Shaw, M.D., MAJ, MC |                 |         |         |         |
| Key Words:   | John J. Perkner, D.O., MAJ, MC  |                 |         |         |         |
| Duodenal ulcer   | James A. Haley, M.D., MAJ, MC   |                 |         |         |         |
|  | Andrew D. Bailey, M.D., CPT, MC |                 |         |         |         |
| Accumulative MEDCASE   | Est Accumulative                | Periodic        |         |         |         |
| Cost:  | OMA Cost:                       | Review Results: |         |         |         |
| Objective: To evaluate the clinical safety and efficacy of Nizatidine in patients with acute duodenal ulcer disease.       |                                 |                 |         |         |         |

Technical Approach: Patients agreeing to participate in the study will initially undergo a complete physical examination to include electrocardiogram, routine blood studies, and urinalysis. They will be randomly assigned to take one capsule of Nizatidine or placebo every 12 hours. Gelusil antacid tablets will be given for relief of any stomach pains. Endoscopy will be done at 2, 4, and 8 weeks.

Progress: This is a new study.

# Detail Summary Sheet

|   |  |                          |                                 |         |         |
|---|--|--------------------------|---------------------------------|---------|---------|
| Date:   | 2 Nov 83                                   | Proj No:                 | C-77-83                         | Status: | Ongoing |
| TITLE:  |  |                          |                                 |         |         |
| High Dose Busulfan with Autologous Bone Marrow Rescue for Solid Malignancies  |  |                          |                                 |         |         |
| Start Date  | 30 Sep 83                                  | Est Comp Date: Sep 84    |                                 |         |         |
| Principal Investigator  | James F. Boyd, M.D., LTC, MC               |                          | Facility                        |         |         |
| Dept/Sec  | Department of Medicine/Hematology-Oncology |                          | Brooke Army Medical Center      |         |         |
| Key Words:  | Bone marrow rescue<br>Busulfan             |                          | Associate Investigators:        |         |         |
|   |  |                          | Roby Joyce, M.D., LTC, MC       |         |         |
|   |  |                          | Glenn M. Mills, M.D., MAJ, MC   |         |         |
|   |  |                          | Walter H. Harvey, D.O., MAJ, MC |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:                 | Periodic Review Results: |                                 |         |         |
| Objective: To study the response rate and toxicity of oral high dose busulfan in malignancies refractory to standard therapy. |  |                          |                                 |         |         |

Technical Approach: Patients agreeing to participate will be admitted to the hospital and a Hickman catheter inserted into a large vein in the region of the shoulder. Following insertion of the catheter, approximately 600-900 cc of marrow will be drawn from the hip bones and stored for transfusion the next day. Approximately 2 hours following the marrow collection, they will be given busulfan orally. The next morning they will receive transfusion of their bone marrow through the Hickman catheter.

Progress: This is a new study.



# Detail Summary Sheet

|  |                                  |                |         |         |         |
|--|----------------------------------|----------------|---------|---------|---------|
| Date:  | 2 Nov 83                         | Proj No:       | C-78-83 | Status: | Ongoing |
| TITLE:   |                                  |                |         |         |         |
| Dexamethasone, Diphenhydramine, Metoclopramide as Antiemetics in Cancer Chemotherapy |                                  |                |         |         |         |
| Start Date   | 30 Sep 83                        | Est Comp Date: | Mar 84  |         |         |
| Principal Investigator   | Facility                         |                |         |         |         |
| Walter H. Harvey, D.O., MAJ, MC  | Brooke Army Medical Center       |                |         |         |         |
| Dept/Sec   | Associate Investigators:         |                |         |         |         |
| Department of Medicine/Hematology-Oncology   | Frederic Lombardo, CPT, MSC      |                |         |         |         |
| Key Words:   | Luke M. Stapleton, M.D., CPT, MC |                |         |         |         |
| Antiemetic   |                                  |                |         |         |         |
| Chemotherapy   |                                  |                |         |         |         |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To determine if this combination of agents will significantly reduce vomiting associated with cancer chemotherapy. |                            |                          |

To compare these results to historical data of patients receiving standard therapy.

Technical Approach: Patients receiving cisplatin, nitrogen mustard, Dacarbazine, Actinomycin-D, or Adriamycin or subsequent chemotherapy with significant vomiting associated are eligible for this study.

Four hours prior to initiation of chemotherapy, patients will receive dexamethasone IV. Three hours later diphenhydramine will be given IV over a 15-30 minute period followed by metoclopramide IV over 15 minutes. Chemotherapy will then be started. Upon completion of chemotherapy, metoclopramide will be given every two hours or until there is no vomiting.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-79-83 Status: Ongoing

## TITLE:

Investigation of Triiodothyronine Dependency Syndrome

|                                      |                                 |
|--------------------------------------|---------------------------------|
| Start Date 30 Sep 83                 | Est Comp Date: Jun 85           |
| Principal Investigator               | Facility                        |
| William J. Georgitis, M.D., MAJ, MC  | Brooke Army Medical Center      |
| Dept/Sec                             | Associate Investigators:        |
| Department of Medicine/Endocrinology | Thomas J. Taylor, M.D., MAJ, MC |
| Key Words:                           |                                 |
| Triiodothyronine dependency syndrome |                                 |
| Hypothyroidism                       |                                 |
| Accumulative MEDCASE Cost:           | Est Accumulative OMA Cost:      |
|                                      | Periodic Review Results:        |

Objective: To establish the existence of a dependency syndrome resulting from chronic, excessive hormone replacement with thyroid extract in the treatment of primary hypothyroidism.

Technical Approach: History and physical examination, thyroid questionnaire, and thyroid profile will be performed on all patients. Based on the results of the thyroid tests, two subgroups will be defined. One group with elevated T3 levels will be called the hyperthyroid group and the second group with normal T3 levels the euthyroid group. Patients will be taken off thyroid extract to correctly identify the presence or absence of primary hypothyroidism and to permit resumption of replacement thyroid hormone as thyroxine at doses titrated to bring the serum TSH within the normal range. Thyroid tests will be done four weeks later and then weekly until TSH elevations greater than 20 occur. At this point a dose of 2.25 mcg/kg ideal body weight of thyroxine will be started. Two weeks later repeat thyroid blood levels will be done and thyroxine dosages adjusted to normalize the thyroid blood tests.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-80-83 Status: Ongoing

## TITLE:

Carbohydrate Malabsorption in the Irritable Bowel Syndrome (IBS)

|                            |   |                          |                             |
|----------------------------|---|--------------------------|-----------------------------|
| Start Date                 | 30 Sep 83                                 | Est Comp Date:           | Apr 84                      |
| Principal Investigator     | John J. Perkner, D.O., MAJ, MC            | Facility                 | Brooke Army Medical Center  |
| Dept/Sec                   | Department of Medicine/Gastroenterology   | Associate Investigators: | Fred Goldner, M.D., LTC, MC |
| Key Words:                 | Malabsorption<br>Irritable bowel syndrome |                          |                             |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:                | Periodic Review Results: |                             |

Objective: To determine if malabsorption of dietary carbohydrate contributes to development of symptoms (bloating, excess flatus and diarrhea in patients with IBS.

Technical Approach: Irritable bowel patients with complaints of bloating, diarrhea and excess gas will be included in the study. Hydrogen breath test will be used to detect carbohydrate malabsorption. The Quintron Microlyzer will be used to measure breath hydrogen.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-83-83 Status: Ongoing

## TITLE:

A Study of Genetic Susceptibility to Mountain Cedar Pollinosis

|   |           |                                  |        |
|---|-----------|----------------------------------|--------|
| Start Date                                | 30 Sep 83 | Est Comp Date:                   | Jul 84 |
| Principal Investigator                    |           | Facility                         |        |
| Daniel A. Ramirez, M.D., LTC, MC          |           | Brooke Army Medical Center       |        |
| Dept/Sec                                  |           | Associate Investigators:         |        |
| Department of Medicine/Allergy-Immunology |           | Neil Boswell, M.D., LTC, MC USAF |        |
| Key Words:                                |           |                                  |        |
| Mountain cedar pollinosis                 |           |                                  |        |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To investigate whether there exists a genetic susceptibility to developing mountain cedar pollinosis, especially in otherwise nonatopic subjects. Two aspects of this problem will be studied:

- Genetic susceptibility to mountain cedar pollinosis as a whole.
- Genetic susceptibility to mountain cedar allergy in patients with no other sensitivities.

Technical Approach: Patients will be selected from a patient population previously identified and characterized. In essence, these patients have had thorough history and physical examination, positive skin tests, and total IgE determined. Blood will be obtained, and tissue typing for A, B, C, and DR antigens will be done.

Progress: This is a new study.

# Detail Summary Sheet

|  |                                   |                          |                                 |                                |         |
|--|-----------------------------------|--------------------------|---------------------------------|--------------------------------|---------|
| Date:  | 2 Nov 83                          | Proj No:                 | C-84-83                         | Status:                        | Ongoing |
| TITLE:   |                                   |                          |                                 |                                |         |
| Evaluation of Systemic and Intracoronary Thrombolytic Therapy in Acute Myocardial Infarction   |                                   |                          |                                 |                                |         |
| Start Date   | 30 Sep 83                         | Est Comp Date:           | Oct 85                          |                                |         |
| Principal Investigator   | David L. Brown, M.D., MAJ, MC     |                          | Facility                        | Brooke Army Medical Center     |         |
| Dept*/Sec  | Department of Medicine/Cardiology |                          | Associate Investigators:        | Stuart Damore, M.D., MAJ, MC   |         |
| Key Words:   | Acute myocardial infarction       |                          | William E. Craig, M.D., MAJ, MC |                                |         |
|  |                                   |                          |                                 | Joseph P. Murgo, M.D., COL, MC |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:        | Periodic Review Results: |                                 |                                |         |
| Objective: To compare the effect of early myocardial reperfusion by intravenous and intracoronary thrombolysis to standard therapy during acute myocardial infarction. |                                   |                          |                                 |                                |         |

Technical Approach: Patients admitted to the Coronary Care Unit will be randomized to one of three treatment arms: 1) standard therapy plus heparinization, 2) peripheral intravenous streptokinase therapy, and 3) intracoronary streptokinase therapy.

Progress: This is a new study.

# Detail Summary Sheet

|  |                            |                                     |         |         |         |
|--|----------------------------|-------------------------------------|---------|---------|---------|
| Date:  | 2 Nov 83                   | Proj No:                            | C-95-83 | Status: | Ongoing |
| TITLE:   |                            |                                     |         |         |         |
| Effect of Micronase on Glucose Control in Poorly Controlled Type II Diabetic Subjects on Insulin Therapy   |                            |                                     |         |         |         |
| Start Date   | 30 Sep 83                  | Est Comp Date: Sep 85               |         |         |         |
| Principal Investigator   |                            | Facility                            |         |         |         |
| Thomas J. Taylor, M.D., MAJ, MC  |                            | Brooke Army Medical Center          |         |         |         |
| Dept/Sec   |                            | Associate Investigators:            |         |         |         |
| Department of Medicine/Endocrinology   |                            | James H. Anderson, Jr., M.D., LTC   |         |         |         |
| Key Words:   |                            | MC                                  |         |         |         |
| Type II diabetic   |                            | William J. Georgitis, M.D., MAJ, MC |         |         |         |
| Insulin therapy  |                            |                                     |         |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results:            |         |         |         |
| Objective: To determine if the addition of Micronase will improve the blood glucose control in Type II (maturity onset) diabetic subjects on insulin therapy but with poor control of blood glucose. |                            |                                     |         |         |         |

Technical Approach: Initially patients will undergo a physical examination and various laboratory studies to include a 3-hour glucose tolerance test. They will then be randomly assigned to receive either Micronase or placebo, one tablet daily before breakfast. Daily dosage will be gradually increased to four tablets. They will continue on this regimen for 16 weeks at which time they will be given the opposite tablet for an additional 16 weeks. Repeat physical examination and laboratory studies will be done prior to the second 16 week trial.

Progress: This is a new study.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-30-82 Status: Terminated  
TITLE:

## Systemic Relaxation Training Group

|  |   |
|--|---|
| Start Date 11 May 82                                       | Est Comp Date:  |
| Principal Investigator<br>Elizabeth A. Bell, R.N., MAJ ANC | Facility<br>Brooke Army Medical Center                      |
| Dept/Sec<br>Department of Nursing                          | Associate Investigators:<br>Harley G. Klein, R.N., MAJ, ANC |
| Key Words:<br>Relaxation training<br>Oncology patients     |   |

|  |                               |                             |
|--|-------------------------------|-----------------------------|
| Accumulative MEDCASE<br>Cost:  | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: |
| Objective: To provide an alternative or adjunctive intervention to oncology patients to deal with their responses to their illness and side effects concomitant with radiation, chemotherapy and/or surgery. |                               |                             |

Technical Approach: Oncology patients are being provided training in systematic relaxation and visualization in a group format. Pre- and post-evaluation is done to determine the patient's current response to illness and other stressors.

Progress: The group of four patients was completed in February 1983. However, one patient terminated with the group. Another group was started, but stopped by mutual agreement. As the investigators were unable to collect an adequate population sample, there is no data for statistical analysis. Subjectively, however, we were able to note some changes in the behavior associated with internal and external stressors associated with the disease process and treatment plan. The three group members verbalized the importance of the social support they received from the group and shared their feelings freely. Difficulty finding sufficient group members, necessitates the termination of the study.

# Detail Summary Sheet

|   |  |                |  |         |           |
|---|--|----------------|--|---------|-----------|
| Date:   | 3 Oct 83   | Proj No:       | C-36-82  | Status: | Completed |
| TITLE:  |  |                |  |         |           |
| Intraoperative Intrauterine Irrigation with Cefamandole Nafate Solution at Cesarean Section versus Intravenous Prophylaxis with Cefoxitin |  |                |  |         |           |
| Start Date  | 26 May 82  | Est Comp Date: |  |         |           |
| Principal Investigator  | Charles A. Jeffreys, Jr., M.D., CPT, MC              |                | Facility   |         |           |
| Dept/Sec  | Department of Obstetrics and Gynecology              |                | Brooke Army Medical Center   |         |           |
| Key Words:  | Intraoperative Irrigation<br>Intravenous Prophylaxis |                | Associate Investigators:<br>Robert L. Wallace, D.O., MAJ, MC<br>C. Neil Herrick, M.D., COL, MC |         |           |

|   |                            |                          |
|---|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: By use of an irrigation solution containing a cephalosporin, the confirmation of its usefulness in decreasing postoperative investments will be assessed. |                            |                          |

To compare the relative effectiveness of intravenous prophylaxis.

To determine if one of the two methods is more appropriate in certain clinical situations.

Technical Approach: Patients undergoing primary or repeat cesarean section at high risk were considered eligible for this study. These patients had spontaneous or augmented labor with ruptured membranes. Patients were randomized in a double-blind fashion into two groups. One group received 2 grams Cefamandole Nafate in 1,000 cc's of normal saline for intrauterine irrigation and four 50 cc bottles of D5W of which one was given intravenously after cord clamping, and then the remainder were given at 6, 12, and 18 hours postoperatively. The second group received 1,000 cc's normal saline for intrauterine irrigation and four 50 cc bottles of D5W with 2.0 grams Cefoxitin in each of which one was given intravenously after cord clamping, and then the remainder given at 6, 12, and 18 hours postoperatively. Irrigation was accomplished in a standard manner utilizing a bulb syringe.

During the postoperative period, each patient was evaluated for development of infection. Any patient suspected of postoperative infection was evaluated with routine laboratory tests to include a white blood cell count, hemoglobin, hematocrit, urinalysis with culture, aerobic and anaerobic blood cultures, and chest x-ray. Also, aerobic and anaerobic cultures were obtained from lochia from the uterine cavity.

Progress: There were 36 patients in the Cefamandole group and 34 in the Cefoxitin group. There was no significant difference in mean age, race, and parity. Fourteen percent of the patients in the Cefamandole irrigation group developed criteria for endoparametritis of which 80% responded to Penicillin



C-36-82 (continued)

and Gentamicin. There was one wound infection in this group, and the same patient developed a cul-de-sac abscess which was subsequently drained via posterior colpotomy. Of the 34 patients who received intravenous Cefoxitin, 12% developed endometritis. Seventy five percent of these patients responded to treatment with Penicillin and Gentamicin. One patient in each of the groups required additional therapy with Clindamycin.

Conclusions: Intrauterine lavage, as well as intravenous prophylaxis has effectively reduced post-cesarean infectious morbidity in this group of high risk patients.

# Detail Summary Sheet

|  |                            |                                       |         |         |           |
|--|----------------------------|---------------------------------------|---------|---------|-----------|
| Date:  | 3 Oct 83                   | Proj No:                              | C-55-82 | Status: | Completed |
| TITLE:   |                            |                                       |         |         |           |
| The Reliability of the Beta Specific Urine Pregnancy Test vs the Radio-immunoassay for Beta-HCG in Serum in the Diagnosis of Ectopic Pregnancy |                            |                                       |         |         |           |
| Start Date   | 13 Aug 82                  | Est Comr Date:                        |         |         |           |
| Principal Investigator   |                            | Facility                              |         |         |           |
| Andrew W. Robertson, M.D., CPT, MC   |                            | Brooke Army Medical Center            |         |         |           |
| Dept/Sec   |                            | Associate Investigators:              |         |         |           |
| Department of Obstetrics and Gynecology  |                            | Edward J. Shumsky, Jr., M.D., LTC, MC |         |         |           |
| Key Words:   |                            | Charles V. Capen, M.D., LTC, MC       |         |         |           |
| Ectopic pregnancy  |                            |                                       |         |         |           |
| Beta specific urine pregnancy test   |                            |                                       |         |         |           |
| Beta-HCG   |                            |                                       |         |         |           |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results:              |         |         |           |
| Objective: To compare the usefulness and reliability of a beta specific urine pregnancy test in the clinical diagnosis of ectopic pregnancy.   |                            |                                       |         |         |           |

Technical Approach: During the period 1 October 1982 thru 31 March 1983, 28 patients were admitted to the gynecology service with the diagnosis of suspected ectopic pregnancy. Baseline laboratory data were obtained on all 28 patients to include a serum and a urine sample for beta-HCG. The serum samples were run on a routine basis (every other day). The urine samples were run on a stat basis by the hospital blood bank personnel. Initially, two separate beta-specific urine pregnancy tests were used, a one hour test (Rx B-Neocept) marketed by Organon and a one hour test (Rx UCG BETA STAT) marketed by Wampole. Results of the first twelve tests were verified by the investigators repeating the tests. The results of the serum tests were later obtained and correlated with the urine results. These results were then compared with the discharge diagnosis and the pathological diagnosis on the specimens obtained at surgery. In the first ten patients, the results of the urine pregnancy test were not used in the initial assessment and clinical management of the patient; whereas in the remaining eighteen patients, the results of the urine pregnancy tests were used in the differential diagnosis and initial management of the patients.

Progress: Of the 28 patients entered on the study, 13 were subsequently proven to have ectopic pregnancies. All 13 patients had positive beta-specific urine and serum pregnancy tests. Four patients (30.7%) were asymptomatic at the time of diagnosis; six patients (46.1%) had unruptured ectopic pregnancies at the time of diagnosis. Culdocentesis was positive in five cases (38.4%), and laparoscopy preceded laparotomy in eight of the cases (61.6%). Conservative surgery was accomplished in four cases (30.7%).

Of the 15 patients who did not have ectopic pregnancies, only two had a positive beta-specific urine pregnancy test. Documentation of a gestational sac on diagnostic ultrasound was obtained on both of the patients thus alleviating the need for further diagnostic evaluation.

Two patients had positive serum tests with a negative urine test. Both were proven to have missed abortions on subsequent dilatation and evacuation specimens.

The remaining 11 patients had negative urine and serum pregnancy tests. Six (54.5%) had positive culdocentesis and required laparotomy. Five (45.5%) patients required either diagnostic ultrasound or diagnostic laparoscopy to confirm the diagnosis.

Conclusions: As a screening test for patients presenting with a history of a missed menstrual period, the beta-specific urine pregnancy test could be used to accurately separate pregnant patients from nonpregnant patients and perhaps symptomatic pregnant patients from nonpregnant patients even if there is no history of a missed menstrual period. However, the numbers in this study are too small to ascribe a statistical significance to this statement.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-58-82 Status: Ongoing

## TITLE:

The Study of Hormonin<sup>R</sup> in the Management of Postmenopausal Symptoms

|                        |   |                          |                                  |
|------------------------|---|--------------------------|----------------------------------|
| Start Date             | 23 Aug 82                               | Est Comp Date:           | Aug 84                           |
| Principal Investigator | C. Neil Herrick, M.D., COL, MC          | Facility                 | Brooke Army Medical Center       |
| Dept/Sec               | Department of Obstetrics and Gynecology | Associate Investigators: | Michael D. Garcia, M.D., CPT, MC |
| Key Words:             | Hormonin<br>Postmenopausal symptoms     |                          |                                  |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objective: To evaluate the comparative short-term efficacy and safety of different Hormonin<sup>R</sup> dosages for the treatment of postmenopausal symptoms in both naturally and surgically menopausal women.

Technical Approach: The study group will be made up of females, age 30-65, who are naturally or surgically menopausal. They will be assigned to one of three groups and will be given one of three dose levels of Hormonin or Premarin or a placebo. The medication will be taken daily for three weeks each month for three months. Endometrial biopsy will be obtained at the first and last visit.

Progress: Fifty patients have been enrolled in the study. Data analysis will not be done until the study has been completed.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-1-83 Status: Ongoing

## TITLE:

Preinduction Cervical Softening with PGE<sub>2</sub> by Administration onto the Vaginal Portion of the Cervix

|   |          |                            |        |
|---|----------|----------------------------|--------|
| Start Date                              | 8 Nov 82 | Est Comp Date:             | Nov 84 |
| Principal Investigator (vice Robertson) |          | Facility                   |        |
| Roger L. Wallace, M.D., MAJ, MC         |          | Brooke Army Medical Center |        |
| Dept/Sec                                |          | Associate Investigators:   |        |
| Department of Obstetrics and Gynecology |          |                            |        |
| Key Words:                              |          |                            |        |
| Preinduction cervical softening         |          |                            |        |
| PGE <sub>2</sub>                        |          |                            |        |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine if PGE<sub>2</sub> in a gel formulation is effective in improving cervical induction features following administration vaginally directly onto the porio vaginalis.

To establish the optimal dose in terms of efficacy and side effects.

Technical Approach: This is a placebo controlled, blinded, randomized, prospective study utilizing Prostaglandin E<sub>2</sub> applied directly to the cervix vs a placebo for patients with medical or obstetrical indications for induction of labor in an unfavorable cervix as determined by the cervical Bishop's score. The Bishop's scoring system is an attempt to objectively evaluate characteristics of the cervix in an effort to predict the likelihood of successful induction and vaginal delivery. This is a cooperative study with the University of Texas Health Science Center here in San Antonio. BAMC has supplied 15 patients on this study.

Progress: The results of the study and data are currently under analysis. There have been no adverse affects noted from the use of the dug. Preliminary data would indicate a significant impact on the Bishop's score after application of PGE<sub>2</sub>, however, whether this significantly shortens the induction to delivery interval or increases the likelihood of vaginal delivery is yet to be determined.

# Detail Summary Sheet

|  |                            |                                  |        |         |         |
|--|----------------------------|----------------------------------|--------|---------|---------|
| Date:  | 2 Nov 83                   | Proj No:                         | C-6-83 | Status: | Ongoing |
| TITLE: Intravenous Piperacillin Sodium vs Penicillin G in Combination with Genatmicin Sulfate and Clindamycin for Postoperative Gynecological and Postpartum Infections              |                            |                                  |        |         |         |
| Start Date   | 10 Nov 82                  | Est Comp Date:                   | May 84 |         |         |
| Principal Investigator   |                            | Facility                         |        |         |         |
| James E. Mark, M.D., MAJ, MC   |                            | Brooke Army Medical Center       |        |         |         |
| Dept/Sec   |                            | Associate Investigators:         |        |         |         |
| Department of Obstetrics and Gynecology  |                            | Charles V. Capen, M.D., LTC, MC  |        |         |         |
| Key Words:   |                            | Averell H. Sutton, M.D., CPT, MC |        |         |         |
| Gynecological infections   |                            |                                  |        |         |         |
| Postpartum infections  |                            |                                  |        |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results:         |        |         |         |
| Objective: To compare with clinical efficacy and cost of a new semi-synthetic Penicillin (Piperacillin) used alone versus that of Penicillin-G, Gentamycin Sulfate, and Clindamycin. |                            |                                  |        |         |         |

Technical Approach: All postoperative Gyn as well as routine obstetrical deliveries and cesarean section patients with clinical evidence of pelvic infection are candidates for the piperacillin study. Patients with non-pelvic source for postoperative febrile morbidity are not candidates. The selected patients are treated with either piperacillin, a combination of penicillin-G, gentamycin and cleocin until resolution of evidence of the pelvic infection. Eighteen patients have been enrolled on the study.

Progress: Because of our very low postoperative infection rate, obtaining patients for the study has been slow. We would like to have a total of 50 patients in the study in an attempt to determine if our results are statistically significant. Trying to define the microbiology for all of our postoperative infections has not been very rewarding thus far. One-half of the patients have received piperacillin and the other half penicillin and gentamycin. The infection cure rates have been just about equal in both groups.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-17-83 Status: Terminated

## TITLE:

Accelerated Clotting Time: A Rapid Evaluation of Fetal Maturity Collected from the Vaginal Pool

|   |   |
|---|---|
| Start Date 3 Mar 83   | Est Comp Date:  |
| Principal Investigator<br>Charles S. Foreman, M.D., CPT, MC | Facility<br>Brooke Army Medical Center                      |
| Dept/Sec<br>Department of Obstetrics and Gynecology         | Associate Investigators:<br>Roger L. Wallace, D.O., MAJ, MC |
| Key Words:<br>Accelerated clotting time<br>Fetal maturity   |   |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To compare the accelerated clotting time to the presence of phosphatidylglycerol from amniotic fluid obtained vaginally.

Technical Approach: The collection of amniotic fluid from the vaginal vault in an attempt to correlate accelerated clotting time with the presence of phosphatidylglycerol from the amniotic fluid therefore indicating fetal maturity was to be done.

Progress: This study was terminated due to inability of principal investigator to complete the study.

# Detail Summary Sheet

|  |                                 |                          |         |         |         |
|--|---------------------------------|--------------------------|---------|---------|---------|
| Date:  | 2 Nov 83                        | Proj No:                 | C-18-83 | Status: | Ongoing |
| TITLE:   |                                 |                          |         |         |         |
| A Double Blind Comparative Study of Ritodrine versus Terbutaline on Arresting Premature Labor                  |                                 |                          |         |         |         |
| Start Date   | 3 Mar 83                        | Est Comp Date:           | Jun 84  |         |         |
| Principal Investigator   | Facility                        |                          |         |         |         |
| George Jirak, M.D., CPT, MC  | Brooke Army Medical Center      |                          |         |         |         |
| Dept/Sec   | Associate Investigators:        |                          |         |         |         |
| Department of Obstetrics and Gynecology  | Roger L. Wallace, D.O., MAJ, MC |                          |         |         |         |
| Key Words:   |                                 |                          |         |         |         |
| Premature labor  |                                 |                          |         |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:      | Periodic Review Results: |         |         |         |
| Objective: To compare the effectiveness of two beta-2 specific receptor agonists on arresting premature labor. |                                 |                          |         |         |         |

Technical Approach: A prospective, randomized, double blind, comparative study of the administration of Ritodrine versus Terbutaline as tocolytic therapy in treating premature labor. Randomization is handled by Pharmacy Service, and the intravenous administration is blinded to the investigators.

Progress: Fifteen patients have been entered on the study. No results are available to date for analysis.



# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-30-83 Status: Terminated

## TITLE:

The Derrick Protocol: The Protocol of Conservative Management of Premature Rupture of Membranes (PROM)

Start Date 19 Apr 83 Est Comp Date:

Principal Investigator Facility

Roderick F. Hume, M.D., CPT, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Obstetrics and Gynecology Roger L. Wallace, D.O., MAJ, MC

Key Words:

Accumulative MEDCASE Est Accumulative Periodic

Cost: OMA Cost: Review Results:

Objectives: The C-reactive protein determinations can be used to identify a low risk group of gravida in terms of ensuing infectious morbidity.

Development of chorioamnionitis is primarily a function of bacteria of enhanced virulence being present as a constituent of the vaginal flora.

Selected bacteriological monitoring will identify the majority of patients with augmented risk.

Prophylactic antibiotics appropriate in spectrum and dose bioavailability will be effective in statistically altering ensuing maternal/neonatal infectious morbidity.

Technical Approach: An attempt will be made to utilize C-reactive protein as an early indicator of the likelihood of developing chorioamnionitis in patients with premature rupture of the membranes.

Progress: This study was terminated due to inability to coordinate technical support in the C-reactive protein determinations.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-50-83 Status: Ongoing

## TITLE:

A Survey of Women Concerning Their Labor and Delivery Experiences

|   |           |                            |        |
|---|-----------|----------------------------|--------|
| Start Date                              | 16 Jun 83 | Est Comp Date:             | Jun 84 |
| Principal Investigator                  |           | Facility                   |        |
| Roger L. Wallace, D.O., MAJ, MC         |           | Brooke Army Medical Center |        |
| Dept/Sec                                |           | Associate Investigators:   |        |
| Department of Obstetrics and Gynecology |           |                            |        |
| Key Words:                              |           |                            |        |
| Birthing Center                         |           |                            |        |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To describe the demographic characteristics of women utilizing the labor, delivery and recovery care facilities at BAMC from October 1982 through May 1983.

To identify women's thoughts and feelings about their labor, delivery, and recovery experiences.

To determine the differences between women who use traditional labor and delivery care facilities and women who use birthing room facilities.

Technical Approach: After field testing a questionnaire, letters were sent to patients delivering using the Birthing Center with a control group constructed of patients of similar parity and age delivery prior to and just after the patient who delivered in the birthing center. We hope to identify specifically areas on which we can impact with prenatal education and preparation for childbirth in order to better prepare patients for their delivery experience.

Progress: One hundred and forty questionnaires have been mailed with 88 responses. Preliminary data are just now being analyzed and compiled.

# Detail Summary Sheet

|  |                                    |                              |                            |         |            |
|--|------------------------------------|------------------------------|----------------------------|---------|------------|
| Date:  | 2 Nov 83                           | Proj No:                     | C-21-80                    | Status: | Terminated |
| TITLE:   |                                    |                              |                            |         |            |
| In vitro Demyelination and Remyelination of Cultured Mammalian Central Nervous Tissue  |                                    |                              |                            |         |            |
| Start Date   | 7 May 80                           | Est Comp Date:               |                            |         |            |
| Principal Investigator   | Roby P. Joyce, M.D., MAJ, MC       |                              | Facility                   |         |            |
| Dept/Sec   | Department of Pathology/Blood Bank |                              | Brooke Army Medical Center |         |            |
| Key Words:   | Central nervous tissue             |                              | Associate Investigators:   |         |            |
|  |                                    | Debra J. Krikorian, CPT, MSC |                            |         |            |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: \$501   | Periodic Review Results:     |                            |         |            |
| Objective: To establish at Brooke Army Medical Center the capability to study demyelination and remyelination of mammalian central nervous tissue in a reliable cell culture laboratory model. |                                    |                              |                            |         |            |

Technical Approach: None.

Progress: Since no progress had been made in three years, the study was terminated due to lack of technical help. Following termination, an individual with expertise in tissue culture techniques was assigned, and the protocol rewritten and approved under research project C-64-83.

# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-22-82 Status: Completed

## TITLE:

Production of Leptospira Hyperimmune Sera in Rabbits

|   |                  |                            |
|---|------------------|----------------------------|
| Start Date                                  | 4 Mar 82         | Est Comp Date:             |
| Principal Investigator                      |                  | Facility                   |
| Michael Gray, M.S.                          |                  | Brooke Army Medical Center |
| Dept/Sec                                    |                  | Associate Investigators:   |
| Department of Pathology/Vet Lab Service     |                  |                            |
| Key Words:                                  |                  |                            |
| Leptospirosis                               |                  |                            |
| Panama Jungle Orientation Training Center   |                  |                            |
| Accumulative MEDCASE                        | Est Accumulative | Periodic                   |
| Cost:                                       | OMA Cost:        | Review Results:            |
| Objective: Production of diagnostic agents. |                  |                            |

Technical Approach: A randomized double-blind placebo-controlled field trial was conducted during the fall of 1982 to determine if doxycycline was an effective chemoprophylactic agent against this infection. Doxycycline (200 mg) or placebo was administered orally on a weekly basis to 940 volunteers from two U.S. Army units deployed to Panama for approximately three weeks of jungle training.

Progress: Twenty cases of leptospirosis occurred in the placebo group (attack rate of 4.2%) compared to only one case in the doxycycline group ( $p < .001$ ), yielding an efficacy of 95.0%. This study demonstrated for the first time the value of doxycycline as a prophylactic drug against leptospirosis.

# Detail Summary Sheet

|  |                            |                            |        |         |           |
|--|----------------------------|----------------------------|--------|---------|-----------|
| Date:  | 3 Oct 83                   | Proj No:                   | C-4-83 | Status: | Completed |
| TITLE:   |                            |                            |        |         |           |
| Determination of Haemophilus Species Antibiotic Sensitivities on the Vitek Gram Positive Susceptibility (GPS) Card                 |                            |                            |        |         |           |
| Start Date   | 10 Nov 82                  | Est Comp Date:             |        |         |           |
| Principal Investigator   |                            | Facility                   |        |         |           |
| William F. Nauschuetz, CPT, MSC  |                            | Brooke Army Medical Center |        |         |           |
| Dept/Sec   |                            | Associate Investigators:   |        |         |           |
| Department of Pathology/Bacteriology   |                            |                            |        |         |           |
| Key Words:   |                            |                            |        |         |           |
| Haemophilus influenzae   |                            |                            |        |         |           |
| GPS card   |                            |                            |        |         |           |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results:   |        |         |           |
| Objective: To determine efficacy of the Enterobacteriaceae Plus Biochemical Card (EBC+) to biotype <u>Haemophilus influenzae</u> . |                            |                            |        |         |           |

Technical Approach: After the study was approved, it was found that the growth rate of H. influenzae in the GPS card did not meet minimal threshold rate to register on the AutoMicrobic System, resulting in change of objectives.

It was then decided to inoculate strains of H. influenzae into EBC+ Cards and then read on the AutoMicrobic System. These were biotyped according to reactions of indole, ornithine decarboxylase, and urease.

Progress: This study showed the EBC+ Card of the AutoMicrobic System to be an accurate and rapid method which can be used to determine the biotype of H. influenzae.

# Detail Summary Sheet

Date: 2 Nov 83 Proj No: C-5-83 Status: Completed

## TITLE:

Comparison of the API Staph Strip and AMS GPI Card for the Identification of Coagulase-Positive and Coagulase-Negative Staphylococci

|                        |                                      |                            |
|------------------------|--------------------------------------|----------------------------|
| Start Date             | 10 Nov 82                            | Est Comp Date:             |
| Principal Investigator | Joyce Rosen, DAC                     | Facility                   |
| Dept/Sec               | Department of Pathology/Bacteriology | Brooke Army Medical Center |
| Key Words:             | API Staph strip                      | Associate Investigators:   |
|                        | AMS GPI Card                         | Maxine Dudley              |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To define, by a head-to-head evaluation, which method is more accurate in the identification of staphylococci.

If they are equally accurate, to decide which method would be more applicable and advantageous to this laboratory, based upon the cost, technician time required, and ease of performance.

Technical Approach: The API 10S System, the Vitek GPI Card and the conventional methods of Kloos and Schleifer simplified scheme were used for the identification of 105 human isolates of Staphylococcus sp.

Progress: The total agreement of API and GPI with the conventional methods was 89.5% and 87.6%, respectively. The species identified by API and GPI were 65/68 and 62/68 for S. epidermidis, 2/2 and 2/2 for S. saprophyticus, 10/13 and 9/13 for S. hominis, 2/3 and 3/3 for S. simulans, 2/2 and 2/2 for S. capitis, 8/12 and 9/12 for S. haemolyticus and 5/5 and 5/5 for S. aureus. The use of coagulase, novobiocin sensitivity, nitrate reduction and/or growth thioglycollate increased the efficacy of both systems.

# Detail Summary Sheet

|  |          |                                 |                                     |                          |         |
|--|----------|---------------------------------|-------------------------------------|--------------------------|---------|
| Date:  | 3 Nov 83 | Proj No:                        | C-64-83                             | Status:                  | Ongoing |
| TITLE:   |          |                                 |                                     |                          |         |
| In vitro Demyelination and Remyelination of Cultured Mammalian Central Nervous Tissue  |          |                                 |                                     |                          |         |
| Start Date   |          |                                 | 10 Aug 83                           |                          |         |
| Principal Investigator   |          |                                 | Est Comp Date:                      |                          |         |
| Roby P. Joyce, M.D., LTC, MC   |          |                                 | Facility                            |                          |         |
| Dept/Sec   |          |                                 | Brooke Army Medical Center          |                          |         |
| Department of Pathology/Blood Bank   |          |                                 | Associate Investigators:            |                          |         |
| Key Words:   |          |                                 | Debra J. Krikorian, Ph.D., CPT, MSC |                          |         |
| Demyelination  |          |                                 |                                     |                          |         |
| Nervous tissue   |          |                                 |                                     |                          |         |
| Accumulative MEDCASE Cost:   |          | Est Accumulative OMA Cost: \$18 |                                     | Periodic Review Results: |         |
| Objectives: To establish the capability of studying demyelination and remyelination of mammalian central nervous tissue <u>in vitro</u> at Brooke Army Medical Center. |          |                                 |                                     |                          |         |

Technical Approach: Myelinated neuronal cultures will be exposed to EAE sera to investigate the process of demyelination at the EM level. The EAE sera will be removed and remyelination will be observed at the EM level in vitro.

Progress: We are currently initiating the tissue culture portion of this project and anticipate beginning the EAE procedures within the next 12 months.

# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-17-82 Status: Ongoing

TITLE:

Beta-Thromboglobulin Levels and Platelet Function in the Newborn

|  |           |                            |        |
|--|-----------|----------------------------|--------|
| Start Date                             | 20 Jan 82 | Est Comp Date:             | Jun 85 |
| Principal Investigator (vice Hallinan) |           | Facility                   |        |
| Terry E. Pick, M.D., LTC, MC           |           | Brooke Army Medical Center |        |
| Dept/Sec                               |           | Associate Investigators:   |        |
| Department of Pediatrics               |           | Isidoro Chapa, DAC         |        |
| Key Words:                             |           |                            |        |
| Beta-thromboglobulin                   |           |                            |        |
| Platelet                               |           |                            |        |

|                      |                   |                          |
|----------------------|-------------------|--------------------------|
| Accumulative MEDCASE | Est Accumulative  | Periodic                 |
| Cost:                | OMA Cost: \$4,269 | Review Results: Continue |

Objectives: To determine the level of Beta-thromboglobulin in the healthy, full-term, and pre-term gestation neonate.

To measure platelet aggregation in this same population.

To determine if a correlation exists between Beta-thromboglobulin levels and platelet aggregation in the term and pre-term gestation neonate.

Technical Approach: Twenty cc of whole blood will be obtained from the umbilical cord of 50 healthy, term infants and 25 pre-term infants. Beta-thromboglobulin determinations will be performed as well as a determination of platelet function.

Progress: Very little progress has been made due to lack of technical help. However, a technician has now been assigned, and we anticipate the generation of helpful data in the near future.



# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-19-83 Status: Ongoing

## TITLE:

Comparison of Efficacy of Theophylline Administered by Continuous Infusion versus Bolus for Status Asthmaticus

|                                 |                 |                            |        |
|---------------------------------|-----------------|----------------------------|--------|
| Start Date                      | 3 Mar 83        | Est Comp Date:             | May 84 |
| Principal Investigator          | (vice Marcille) | Facility                   |        |
| William H. Parry, M.D., COL, MC |                 | Brooke Army Medical Center |        |
| Dept/Sec                        |                 | Associate Investigators:   |        |
| Department of Pediatrics        |                 |                            |        |
| Key Words:                      |                 |                            |        |
| Status asthmaticus              |                 |                            |        |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine which of two methods of IV Theophylline administration is more effective in reversing status asthmaticus.

Technical Approach: Theophylline will be administered in a double-blind fashion, ie. initially all patients will receive a bolus of 6 mg/kg over 20 minutes. One-half of the patient population, chosen at random, will receive a bolus of 5 mg/kg every 4 hours; the other half will receive a continuous infusion of 1 mg/kg per hour of Theophylline after the initial bolus. The study will end at 24 hours.

Progress: CPT Marcille was transferred and unable to complete the study. No reportable data was available prior to her departure.

# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-20-83 Status: Completed

## TITLE:

Effect of Diet on Childhood Migraines

|                                 |          |                            |
|---------------------------------|----------|----------------------------|
| Start Date                      | 3 Mar 83 | Est Comp Date:             |
| Principal Investigator          |          | Facility                   |
| Wanda J. Venters, M.D., CPT, MC |          | Brooke Army Medical Center |
| Dept/Sec                        |          | Associate Investigators:   |
| Department of Pediatrics        |          |                            |
| Key Words:                      |          |                            |
| Diet                            |          |                            |
| Childhood migraines             |          |                            |

|                      |                  |                 |
|----------------------|------------------|-----------------|
| Accumulative MEDCASE | Est Accumulative | Periodic        |
| Cost:                | OMA Cost:        | Review Results: |

Objective: An attempt will be made to discover the effect of diet on the frequency and severity of childhood migraines.

**Technical Approach:** The study was designed to determine, in children, the effect of foods which are most frequently reported to cause migraines: cheese, chocolate, meats preserved with nitrates (bologna, ham, bacon, etc.), citrus fruits, nuts, milk and caffeine.

Five males and six females were enrolled in the study with headaches ranging in frequency from daily to weekly. Five patients were deleted from the study due to insufficient follow-up. Of the six patients who were followed for periods of two to six months, one patient received no benefit from the elimination diet and was begun on amitryptiline for prophylaxis.

All patients eliminated cheese, chocolate, caffeine, nitrate meats, citrus fruits, nuts (including peanut butter), and milk from their diet for two weeks. If headaches did not decrease, the patient continued avoiding all these food for two additional weeks. If there was a resolution of headaches, one of the foods indicated above was added to the patient's diet every two weeks. If the patient then had an increase in headaches, the most recently added food was eliminated and headache frequency monitored.

**Results:** In four of the six patients studied, chocolate, nuts and caffeine were the most frequent causes of migraine. In one patient, the avoidance of cheese, chocolate, nitrate meats and caffeine resulted in her being headache free for six weeks. One patient showed no improvement.

# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-24-83 Status: Completed

## TITLE:

Gentamicin in the Low Birth Weight Neonate

|                            |  |                            |
|----------------------------|--|----------------------------|
| Start Date                 | 16 Mar 83                              | Est Comp Date:             |
| Principal Investigator     | Eduardo J. Lugo, M.D., CPT, MC         | Facility                   |
| Dept/Sec                   | Department of Pediatrics               | Brooke Army Medical Center |
| Key Words:                 | Gentamicin<br>Low birth weight neonate | Associate Investigators:   |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:             | Periodic Review Results:   |

Objective: By following peak and trough Gentamicin blood levels in neonates weighing less than 2500 grams under a recommended standardized dosage regimen, determine differences in blood levels between different groups of low and very low birth weight neonates (500-1199 grams, 1200-1799 grams, and 1800-2499 grams), to check for appropriateness of such dosage regimen in each of the groups.

Technical Approach: Every newborn infant weighing less than 2500 grams with suspected or documented bacterial infection was started on a regimen of Gentamicin 2.5 mg per kilo every 18 hours given intravenously or through umbilical artery catheter every twenty minutes. Patients in renal failure (defined as urine output less than 0.5 cc per kilo per hour, plus proteinuria, hematuria, or both) were excluded or dropped from the study.

Pre-dose and one hour post-dose Gentamicin serum concentrations were determined for the 54 and 72 hour doses, when steady state was assumed to be reached. Gentamicin serum concentrations were determined by the homogenous enzyme immunoassay method.

Weight, urine output, urinalysis, serum electrolytes, serum creatinine, and BUN were monitored daily.

Results: A total of 28 neonates were included in the study. Eleven were in the less than 1200 gram group, 9 in the 1200 to 1799 gram group, and 8 in the 1800 to 2499 gram group.

The regimen of 2.5 mg/kilo of Gentamicin every 18 hours seems to be a good starting point in neonates weighing less than 2500 grams at birth during the first week of life, but with the need to monitor periodically pre-dose and post-dose serum concentrations in all patients.

# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-34-83 Status: Completed  
 TITLE:

Orthostatic Blood Pressure and Heart Rate Changes in Children

|   |   |
|---|---|
| Start Date 19 Apr 83  | Est Comp Date:                                      |
| Principal Investigator<br>Wilfred Castro-Reyes, M.D., CPT, MC | Facility<br>Brooke Army Medical Center              |
| Dept/Sec<br>Department of Pediatrics                          | Associate Investigators:                            |
| Key Words:<br>Orthostatic blood pressure<br>Heart rate        |   |
| Accumulative MEDCASE Cost:                                    | Est Accumulative OMA Cost: Periodic Review Results: |

Objective: To obtain data on normal blood pressure and heart rate changes from the supine to the standing position in children.

Technical Approach: The patient's left upper arm circumference and length were measured and a blood pressure cuff which had a width at least 40% of the upper arm's circumference and a length approximately equal to the arm's circumference was selected. The heart rate monitor leads were connected to the patient's extremities, and the blood pressure cuff was placed on the left arm for convenience. The child would then lay down on the table and remain in the supine position for at least three minutes and until the heart rate had been stable  $\pm$  three beats per minute for one minute. During this period, the blood pressure cuff was inflated and deflated several times to allow the child to get used to this procedure. Once the heart rate had been stable, it was recorded from the monitor screen, and the blood pressure was determined by auscultation, recording the 1st, 4th and 5th Korotkoff sounds. Then the patient was asked to stand on the floor, or in the case of a small child, on the table. The heart rate and blood pressure were determined at one minute intervals, for five consecutive readings starting one minute after assuming the standing position.

Progress: Upon standing from the supine position, hemodynamic adjustments in the body occur. With a significant deficit of intravascular volume, a few minutes may be required before an abnormal change in heart rate or blood pressure is detected. The exact time to determine the heart rate and blood pressure after standing, in order to best differentiate normovolemic from volume depleted patients, is unknown. This study shows that in normovolemic children, all changes in heart rate and blood pressure that may occur upon standing, have done so by two minutes.

For the 2 to 8 year old children the normal increase in heart rate upon standing up from the supine position may be as great as 30 beats per minute.

C-34-83 (continued)

For the 9 to 12 year old children, this increase may be as great as 40 beats per minute. Thus, during an orthostatic test, a heart rate increment within the above limits cannot be used as evidence suggestive of an intravascular volume deficit.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-69-83 Status: Ongoing

## TITLE:

A Study of the Inheritance Patterns of Classical 21-Hydroxylase Deficiency and Related Alleles

|                        |                                  |                          |                            |
|------------------------|----------------------------------|--------------------------|----------------------------|
| Start Date             | 9 Sep 83                         | Est Comp Date:           | Feb 84                     |
| Principal Investigator | Thomas A. Perkins. D.O., CPT, MC | Facility                 | Brooke Army Medical Center |
| Dept/Sec               | Department of Pediatrics         | Associate Investigators: |                            |
| Key Words:             | 21-Hydroxylase deficiency        |                          |                            |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To study individuals at risk of late onset and cryptic 21-Hydroxylase deficiency as well as families with documented classical salt-losing 21-Hydroxylase deficiency.

Technical Approach: Families who have either the classical 21-Hydroxylase deficiency and/or the late onset 21-Hydroxylase deficiency will be studied. Members will be screened first with HLA typing and the 17-Hydroxy-progesterone response to ACTH stimulation. Normal members of the family will serve as controls.

Progress: This is a new study.

# Detail Summary Sheet

|  |  |                          |
|--|--|--------------------------|
| Date: 3 Nov 83   | Proj No: C-12-77   | Status: Ongoing          |
| TITLE: Intravenous Administration of <sup>131</sup> I (NP 59) for Adrenal Evaluation of Imaging.   |  |                          |
| Start Date 15 Nov 76   | Est Comp Date: Not known   |                          |
| Principal Investigator<br>Steven Bunker, M.D. MAJ, MC  | Facility<br>Brooke Army Medical Center   |                          |
| Dept/Sec<br>Department of Radiology/Nuclear Medicine   | Associate Investigators:<br>Roswell N. Beck, Jr., M.D., MAJ, MC<br>Ronald K. McCauley, M.D., MAJ, MC |                          |
| Key Words:<br>Adrenal scan, NP-59  |  |                          |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:   | Periodic Review Results: |
| Objective: Clinical evaluation of NP-59 as a diagnostic agent for the detection of adrenal-cortical disorders and as a potential scanning agent for detecting structural abnormalities of the adrenal medulla. |  |                          |

Technical Approach: The patient is injected I.V. with 1-2 millicuries of I-131 labeled NP 59. Scanning over the adrenal glands is performed at 3 days and again at approximately 7 days after injection. Visual image interpretation as well as computer enhanced processing of the images is used to evaluate them. In selected patients, two repeat studies employing dexamethasone suppression may also be performed.

Progress: During the period 1 October 1982 through 30 September 1983, no studies were performed. Although no usage has been demonstrated, we do wish to continue our status as authorized users under the current protocol should diagnostic need for the product arise.

# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-10-83 Status: Ongoing

## TITLE:

Hepatic Ablation with Absolute Ethanol in Dogs.

|  |   |
|--|---|
| Start Date 6 Jan 83                                      | Est Comp Date: Jan 84   |
| Principal Investigator<br>Arthur L. Fritz, M.D., MAJ, MC | Facility<br>Brooke Army Medical Center  |
| Dept/Sec<br>Department of Radiology/Special Procedures   | Associate Investigators:<br>Frank P. Wilson, M.D., MAJ, MC<br>Walter H. Harvey, D.O., MAJ, MC<br>Michael Hartshorn, M.D., MAJ, MC |
| Key Words:<br>Hepatic ablation                           |   |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To evaluate the morbidity of partial hepatic ablation with absolute ethanol and the pathology of the response by the liver.

Technical Approach: Nine mongrel dogs were anesthetized with 2 mg/kg Nembuto and maintained on spontaneous respirations. Selective and subselective branches of the hepatic artery were infused with varying doses of USP alcohol. Pre and post embolization serum hepatic enzyme determinations were obtained. Repeat arteriography was performed on the surviving animals; and in one nuclear medicine liver-spleen scan utilizing Technetium labeled macroaggregated albumin and sulfur colloid were obtained.

Progress: Initial experience infusing 10-15 cc of absolute ethanol into a branch of the hepatic artery resulted in hemorrhagic necrosis of that corresponding part of the liver, and death. Subsequently, much smaller volumes of alcohol, 1-2 cc has led to animal survival and limited partial hepatic ablation. Nuclear medicine studies will be of great value in following and documenting the pathological response, physiologically, of the liver in response to arterial infusion of alcohol.



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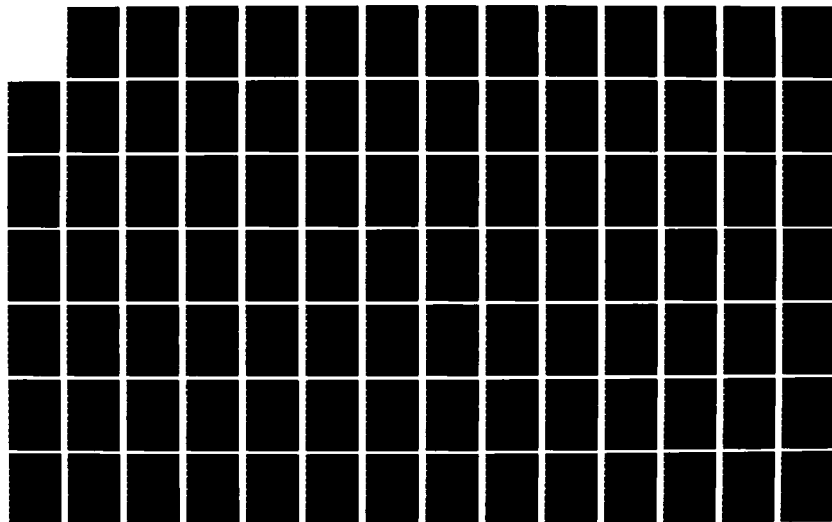
ANNUAL RESEARCH PROGRESS REPORT FOR FISCAL YEAR 1983  
(U) BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TX  
J H ANDERSON 01 OCT 83

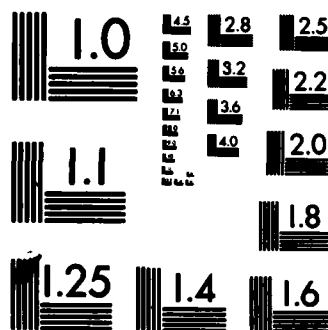
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MICROCOPY RESOLUTION TEST CHART  
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# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-58-63 Status: Ongoing

## TITLE:

Evaluation of Indium Oxine In-III Labeled Cellular Blood Components

|                            |  |                          |  |
|----------------------------|--|--------------------------|--|
| Start Date                 | 10 Aug 83                                | Est Comp Date:           | Oct 84   |
| Principal Investigator     | Stephen R. Bunker, M.D., MAJ, MC         | Facility                 | Brooke Army Medical Center   |
| Dept/Sec                   | Department of Radiology/Nuclear Medicine | Associate Investigators: | Michael Hartshorne, M.D., MAJ, MC<br>Alfred J. Landry, R.Ph., MAJ, MSC |
| Key Words:                 | Labeled cellular blood components        |                          |  |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:               | Periodic Review Results  |  |

Objective: To evaluate the clinical usefulness of Indium Oxine labeled cellular blood components in infections, vascular and platelet disorders.

Technical Approach: A series of 200 patients who fulfill the criteria for admission to the study will be injected with a maximum of 1 mCi of Indium-111 labeled to either homologous or autologous cellular blood components. A dose of 0.5 to 1 mCi will be administered intravenously. Imaging with a gamma camera equipped with a medium energy collimator will usually start 24 hours post injection. This procedure will be followed for inflammation detection.

Indium-111 labeled platelets will be administered intravenously in 200 patients suspected of having venous or arterial thrombi and in patients where platelet survival studies may be indicated. Whole body scans will be carried out at intervals of 3, 24, and 48 hours post injection or as required to maximize diagnostic information.

Progress: Since obtaining the IND, ten studies have been performed. To date there have been no adverse or allergic reactions to the Indium-111 labeled cells. Although it is premature to reach any valid conclusions concerning this study, we feel very strongly that the study is useful and should contribute significantly to the support of patient care.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-82-83 Status: Ongoing

## TITLE:

Pediatric Urography: Open Clinical Trial with Iohexol in Patients No More Than Six Years of Age

|                             |                            |                            |        |
|-----------------------------|----------------------------|----------------------------|--------|
| Start Date                  | 30 Sep 83                  | Est Comp Date:             | Oct 85 |
| Principal Investigator      |                            | Facility                   |        |
| Rosa Ramirez, M.D., MAJ, MC |                            | Brooke Army Medical Center |        |
| Dept/Sec                    |                            | Associate Investigators:   |        |
| Department of Radiology     |                            | Robert L. Siegle, M.D.     |        |
| Key Words:                  |                            |                            |        |
| Urography                   |                            |                            |        |
| Iohexol                     |                            |                            |        |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results:   |        |

Objectives: To evaluate the safety of iohexol in intravenous urography in pediatric patients less than seven years of age by measuring changes in vital signs, changes in blood and urine chemistries, and recording adverse reactions.

To evaluate the quality of radiographic visualization afforded by iohexol in intravenous urography in pediatric patients less than seven years of age.

Technical Approach: Patients scheduled for urography are eligible. Iohexol is injected into the vein and x-rays obtained. Blood sample will be obtained before the dye is given and at 24 and 48 hours after the dye is given. A urine sample will also be collected at these times, and at 6 hours after the dye is given.

Progress: This is a new study.

# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-21-78 Status: Ongoing

## TITLE:

Clinical Study of Intraocular Lenses.

|  |  |
|--|--|
| Start Date Feb 78  | Est Comp Date: Unknown                                     |
| Principal Investigator (vice Gearhart)<br>Donald Bode, M.D., COL, MC | Facility<br>Brooke Army Medical Center                     |
| Dept/Sec<br>Department of Surgery/Ophthalmology                      | Associate Investigators:<br>Donald Griffith, M.D., COL, MC |
| Key Words:<br>Intraocular lens<br>Cataract extraction                |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: To establish the safety and effectiveness of this device for use in human subjects according to guidelines recommended by the Food and Drug Administration ophthalmic advisory panel.

Technical Approach: Pursuant to protocols approved by the FDA, all have selected suitable patients for insertion of both posterior chamber and anterior chamber intraocular lenses. Using standard surgical techniques, these lenses were inserted as part of a cataract operation. All reporting required by the FDA has been completed.

Progress: A total of 466 lense have been inserted (166 during FY 83). Between 40-45 were inserted by each third year resident. Complication with lenses did not significantly exceed those without lenses. Only one lens was removed for late complications. Follow-up on that case is adequately long to determine the final vision. Preliminary outlook is good with driving vision.

# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-14-80 Status: Terminated

## TITLE:

Abdominal Wound Closure

|                            |   |   |
|----------------------------|---|---|
| Start Date                 | Mar 80  | Est Comp Date:  |
| Principal Investigator     | Michael J. Walters, M.D., LTC, MC                     | Facility  |
| Dept/Sec                   | Department of Surgery/General Surgery                 | Brooke Army Medical Center                            |
| Key Words:                 | Running suture<br>Interrupted suture<br>Wound closure | Associate Investigators:<br>General Surgery Residents |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:                            | Periodic Review Results:                              |

Objective: To determine if there is a difference in wound closures performed by interrupted or running suture techniques on the fascial layers.

Technical Approach: Wound closure techniques are evaluated for: (a) time of closure at operation and (b) immediate and long-term postoperative wound complications.

Progress: Data accumulation has been incompleated and interest in this study has waned since the retirement of the original investigator who submitted the study.

# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-7-81 Status: Completed

## TITLE:

Open-ended Cutaneous Vasostomy

|                                |                            |                                  |
|--------------------------------|----------------------------|----------------------------------|
| Start Date                     | 3 Feb 81                   | Est Comp Date:                   |
| Principal Investigator         |                            | Facility                         |
| Mauro P. Gangai, M.D.          |                            | Brooke Army Medical Center       |
| Dept/Sec                       |                            | Associate Investigators:         |
| Department of Surgery/Urology  |                            | C. Ritchie Spence, M.D., COL, MC |
| Key Words:                     |                            |                                  |
| Spermatic granuloma            |                            |                                  |
| Open-ended cutaneous vasostomy |                            |                                  |
| Accumulative MEDCASE Cost:     | Est Accumulative OMA Cost: | Periodic Review Results:         |

Objective; To avoid the major complications, such as spermatic granuloma of the vas, epididymal discomfort and pain due to intravasal pressure buildup and spontaneous recanalization which often occur in patients who have a vas-ectomy performed in the conventional manner for surgical sterility.

Technical Approach: Open-ended vasostomy is performed by isolating the vas deferens in a standard fashion and using vaso-clips on the distal end of the vas. The proximal vas is spatulated and sutured in an open fashion to the scrotal skin.

Progress: The study was discontinued. Over the past year there has been decreasing enthusiasm for the project because of an unacceptable incidence of complications, primarily epididymitis requiring hospitalization for 4-7 days followed by convalescent leave of 1-2 weeks. The morbidity at times seemed worse than the spermatic granuloma complications that we were trying to prevent.

# Detail Summary Sheet

|   |                                   |                          |          |         |         |
|---|-----------------------------------|--------------------------|----------|---------|---------|
| Date:   | 3 Nov 83                          | Proj No:                 | C-22-81  | Status: | Ongoing |
| TITLE:  |                                   |                          |          |         |         |
| The Effect of Prophylactic Antibiotics on Wound Sepsis Following Elective Cholecystectomy |                                   |                          |          |         |         |
| Start Date  | 26 Mar 81                         | Est Comp Date:           | Jun 84   |         |         |
| Principal Investigator  | Facility                          |                          |          |         |         |
| Cheryl A. Wesen, M.D., CPT, MC  | Brooke Army Medical Center        |                          |          |         |         |
| Dept/Sec  | Associate Investigators:          |                          |          |         |         |
| Department of Surgery/General Surgery   | Michael J. Walters, M.D., LTC, MC |                          |          |         |         |
| Key Words:  |                                   |                          |          |         |         |
| Prophylactic antibiotics  |                                   |                          |          |         |         |
| Cholecystectomy   |                                   |                          |          |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:        | Periodic Review Results: | Continue |         |         |

Objective: To determine if the use of prophylactic, broad-spectrum antibiotics will significantly decrease the incidence of wound sepsis following elective cholecystectomy for chronic cholecystitis and/or cholelithiasis.

Technical Approach: Patients undergoing elective cholecystectomy will be randomized into control and study groups. The control group will receive no antibiotics. The study group will receive intravenous Cefamandole immediately prior to surgery and 6 and 12 hours after surgery. Cultures of bile for aerobes and anaerobes will be obtained intraoperatively. Patients will be followed postoperatively for signs and symptoms of wound sepsis.

Progress: Little or no progress has been made during FY 83 due to the principal investigator rotating through other services. Now that these are complete, it is anticipated that patient enrollment on the study will be markedly increased.



# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-30-81 Status: Terminated  
TITLE:

Renal Sequelae of Vasectomy

|                            |                                |   |
|----------------------------|--------------------------------|---|
| Start Date                 | 10 Apr 81                      | Est Comp Date:  |
| Principal Investigator     | Ian M. Thompson, M.D., CPT, MC | Facility  |
| Dept/Sec                   | Department of Surgery/Urology  | Brooke Army Medical Center  |
| Key Words:                 | Vasectomy<br>Renal sequelae    | Associate Investigators:<br>Mauro P. Gangai, M.D.<br>C. Ritchie Spence, M.D., COL, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:     | Periodic Review Results:  |

Objective: To determine, in a retrospective manner, if any changes in renal function occur after vasectomy.

Technical Approach: We will compare patients with history of vasectomy to age matched controls using 24 hour creatinine/protein clearances as a measure of renal function.

Progress: This study was terminated as patient acquisition became a significant problem.

# Detail Summary Sheet

|  |                                       |                          |                            |         |            |
|--|---------------------------------------|--------------------------|----------------------------|---------|------------|
| Date:  | 16 Nov 83                             | Proj No:                 | C-32-81                    | Status: | Terminated |
| TITLE:   |                                       |                          |                            |         |            |
| The Role of Continuous Peritoneal Lavage in the Treatment of Severe Acute Pancreatitis   |                                       |                          |                            |         |            |
| Start Date   | 12 May 81                             | Est Comp Date:           |                            |         |            |
| Principal Investigator   | James M. Kunkel, M.D., CPT, MC        |                          | Facility                   |         |            |
| Dept/Sec   | Department of Surgery/General Surgery |                          | Brooke Army Medical Center |         |            |
| Key Words:   | Pancreatitis<br>Peritoneal lavage     |                          | Associate Investigators:   |         |            |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:            | Periodic Review Results: |                            |         |            |
| Objective: To determine the efficacy of continuous peritoneal lavage in decreasing the morbidity and mortality of severe acute pancreatitis. |                                       |                          |                            |         |            |

Technical Approach: Patients diagnosed as having severe, acute pancreatitis will be randomized into control and study groups. The control group will receive standard care for pancreatitis with surgical intervention when appropriate. The study group will undergo continuous peritoneal lavage with Inpersol for not less than 48 hours and no more than 5 days.

Progress: One patient has been enrolled and treated with peritoneal lavage. The patient did well. No new patients have been studied during the past year. Therefore, the study is terminated due to insufficient number of patients.

# Detail Summary Sheet

|  |                                      |                          |                            |         |         |
|--|--------------------------------------|--------------------------|----------------------------|---------|---------|
| Date:  | 3 Nov 83                             | Proj No:                 | C-41-81                    | Status: | Ongoing |
| TITLE:   |                                      |                          |                            |         |         |
| Hearing Levels in Otherwise Healthy Children Who Were Exposed to Ultrasound While Fetuses                                  |                                      |                          |                            |         |         |
| Start Date   | 15 Jun 81                            | Est Comp Date:           | Mar 84                     |         |         |
| Principal Investigator   | Leonard Brown, M.D., CPT, MC         | Facility                 | Brooke Army Medical Center |         |         |
| Dept/Sec   | Department of Surgery/Otolaryngology | Associate Investigators: |                            |         |         |
| Key Words:   | Ultrasound                           |                          |                            |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:           | Periodic Review Results: | Continue                   |         |         |
| Objective: To measuring hearing levels of otherwise healthy children who underwent diagnostic ultrasound <u>in utero</u> . |                                      |                          |                            |         |         |

Technical Approach: Complete history and physical are performed on patients with history of ultrasonography in utero. This is followed by high frequency and routine audiometric testing.

Progress: Majority of study group has been obtained. However, there is greater than anticipated difficulty in obtaining controls. There have been no adverse side effects, and several unrelated disorders have been diagnosed and treated.

# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-57-81 Status: Ongoing

## TITLE:

Cardiac Surgery Prospective Follow-up Project

|                            |                                      |                          |                            |
|----------------------------|--------------------------------------|--------------------------|----------------------------|
| Start Date                 | 20 Aug 81                            | Est Comp Date:           | Aug 84                     |
| Principal Investigator     | James B. Peake, M.D., COL, MC        | Facility                 | Brooke Army Medical Center |
| Dept/Sec                   | Department of Surgery/Cardiothoracic | Associate Investigators: |                            |
| Key Words:                 | Cardiac surgery                      |                          |                            |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:           | Periodic Review Results: | Continue                   |

Objectives: To follow-up patients who have had cardiac surgical procedures to assess: a. short-term outcome; b. long-term outcome; c. prognostic factors and relate above to work status and military service.

Technical Approach: We continue to register patients undergoing heart surgery requiring extracorporeal circulation.

Follow-up letters are being sent at between 1 and 1½ years with a 70% response rate. Because of lack of clerical support, follow-up on non-responders has not been accomplished.

A total of 1,150 patients have been enrolled on this study (450 during FY 83).

Progress: We have recently pulled all active duty patients for detailed follow-up as a separate sub-group. These patients will have an intensive attempt.

# Detail Summary Sheet

|   |  |                       |                                      |         |         |
|---|--|-----------------------|--------------------------------------|---------|---------|
| Date:   | 3 Nov 83                                   | Proj No:              | C-6-82                               | Status: | Ongoing |
| TITLE:  |  |                       |                                      |         |         |
| Antibiotic Prophylaxis for Transurethral Resection of the Prostate TURP.  |  |                       |                                      |         |         |
| Start Date  | 21 Oct 81                                  | Est Comp Date: Oct 84 |                                      |         |         |
| Principal Investigator  | Ian M. Thompson, M.D., CPT, MC             |                       | Facility                             |         |         |
| Dept/Sec  | Department of Surgery/Urology              |                       | Brooke Army Medical Center           |         |         |
| Key Words:  | Transurethral resection of prostate (TURP) |                       | Associate Investigators:             |         |         |
| Prophylaxis   | Antibiotics                                |                       | C. Kenneth McAllister, M.D., LTC, MC |         |         |
| Accumulative MEDCASE  |  | Est Accumulative      | Periodic                             |         |         |
| Cost:   | OMA Cost:                                  |                       | Review Results: Continue             |         |         |
| Objective: To determine if a rationale exists for the prophylactic use of antibiotics prior to and during transurethral resection of the prostate (TURP). |  |                       |                                      |         |         |

Technical Approach: This is a randomized, double blinded placebo controlled study of Septra (2 doses preop/2 doses postop) for TURP in low-risk patients.

Progress: The study is progressing well although many patients have been excluded due to previous antibiotic therapy. Four new patients were enrolled on the study during FY 83 giving a total of 17.

# Detail Summary Sheet

Date: 3 Nov 83 Proj No: C-14-82 Status: Terminated  
 TITLE:

Association of Genitourinary Tract Abnormalities with Inguinal Hernia  
 and Prognosis of Inguinal Hernia Repair

|   |  |
|---|--|
| Start Date Jan 82   | Est Comp Date:                         |
| Principal Investigator<br>John K. Hamelink, M.D., CPT, MC | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department of Surgery/General Surgery         | Associate Investigators:               |
| Key Words:  |  |

|                               |                               |                             |
|-------------------------------|-------------------------------|-----------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: |
|-------------------------------|-------------------------------|-----------------------------|

Objective: To determine the degree of association of genitourinary tract abnormalities and inguinal hernia. Also to attempt to identify any association that may exist between genitourinary tract abnormalities and prognosis of inguinal hernia repair.

Technical Approach: None.

Progress: Terminated due to lack of interest on the part of the principal investigator to continue the study.

# Detail Summary Sheet

|   |                                  |                          |  |         |         |
|---|----------------------------------|--------------------------|--|---------|---------|
| Date:   | 15 Nov 83                        | Proj No:                 | C-20-82  | Status: | Ongoing |
| TITLE:<br>Long-Term Effect of Orthoptics on the Fusional Vergences.   |                                  |                          |  |         |         |
| Start Date  | 16 Feb 82                        | Est Comp Date: Dec 85    |  |         |         |
| Principal Investigator  | John C. Kotulak, O.D., CPT, MSC  |                          | Facility<br>Brooke Army Medical Center   |         |         |
| Dept/Sec  | Department of Surgery/Optomtry   |                          | Associate Investigators:<br>William B. Knapp, O.D., Ph.D. CPT, MSC<br>Mark D. Cooney, O.D., CPT, MSC |         |         |
| Key Words:  | Orthoptics<br>Fusional Vergences |                          |  |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:       | Periodic Review Results: |  |         |         |
| Objective: To determine the long-range efficacy or permanency of orthoptics as a treatment modality for strabismus. |                                  |                          |  |         |         |

Technical Approach: All subjects are trained according to Orthoptic procedure consistent with those methods espoused by John Griffin in his book Binocular Anomalies - Procedures For Vision Therapy. These are classical treatment modalities which are, in and of themselves, noncontroversial and noninvasive and associated with no risk to the patient.

Progress: Thirty-five patients have been entered on the study (15 during FY 83). Progress can be summarized simply in increased data accumulation.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-34-82 Status: Ongoing

## TITLE:

Preoperative Detection of Gram Negative Pathogens in Intraocular Surgery Candidates.

|  |  |
|--|--|
| Start Date 18 May 82                                     | Est Comp Date: Sep 84                                    |
| Principal Investigator<br>Don G. Griffith, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Surgery/Ophthalmology          | Associate Investigators:<br>Vern Juchau, Ph.D., LTC, MSC |
| Key Words:<br>Limulus lysate<br>Conjunctiva              |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: To utilize Limulus Lysate screening to detect the presence of gram negative organisms in and around the eye in patients scheduled for ocular surgery. Patients will have simultaneous cultures performed to correlate bacteriologic growth and potential pathogenicity with positive Limulus Lysate Test results.

Technical Approach: Fourteen patients have been entered on the study (none in FY 83). Limulus Lysate is inoculated with swabs from subject's conjunctiva.

Progress: Due to technical problems, predominantly false positive controls, no new patients have been enrolled. Unless this can be overcome, we will terminate the study due to lack of practical clinical applicability.



# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-41-82 Status: Ongoing

## TITLE:

Color Defects in Glaucoma.

|  |  |
|--|--|
| Start Date 7 Jul 82  | Est Comp Date: Sep 84                  |
| Principal Investigator (vice gearhart)<br>Donald Bode, M.D., COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department of Surgery/Ophthalmology                      | Associate Investigators:               |
| Key Words:<br>Color vision<br>Glaucoma                               |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: Assess the relationship between glaucoma and color vision defects. Primary emphasis will be on the correlation of early color vision defects with other signs of glaucoma, such as visual field changes and optic disc changes. The prognostic significance of color vision defects in the early glaucoma and ocular hypertensive groups will also be evaluated.

Technical Approach: Visual fields and Farnsworth-Munsell hue tests will be analyzed to determine whether the latter will be predictive in glaucoma. No work has been done while awaiting equipment.

Progress: The equipment has been received; however, no patients have been studied.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-12-83 Status: Ongoing

## TITLE:

Is Routine Intraoperative Cholangiography (IOC) a Useful Adjunct to Cholecystectomy?

Start Date 3 Jan 83 Est Comp Date: Jan 86

Principal Investigator Facility

Daniel Rosenthal, M.D., COL, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Surgery/General Surgery

## Key Words:

Intraoperative holangriography

Cholecystectomy

Accumulative MEDCASE Est Accumulative Periodic

Cost: OMA Cost: Review Results:

Objective: To determine if routine IOC significantly alters the management of patients with cholecystolithiasis by demonstrating at operation the presence of unsuspected stones in the biliary tree.

Technical Approach: All medical centers using routine IOC will be asked to participate. On a quarterly basis, they will be asked to report the number of IOCs performed, number of normals, what was done, and the number of minutes added to the procedure.

Progress: We are presently accumulating data and will start looking at the results when we reach 250 operative cholangiograms. This should take approximately 12 to 18 months.

# Detail Summary Sheet

|   |  |                          |  |         |           |
|---|--|--------------------------|--|---------|-----------|
| Date:   | 15 Nov 83  | Proj No:                 | C-13-83  | Status: | Completed |
| TITLE:  |  |                          |  |         |           |
| Bladder Surface Mucin - Impact on Implantation of Transitional Cell Carcinoma   |  |                          |  |         |           |
| Start Date  | 6 Jan 83   | Est Comp Date:           |  |         |           |
| Principal Investigator  | Ian M. Thompson, M.D., CPT, MC                       |                          | Facility   |         |           |
| Dept/Sec  | Department of Surgery/Urology                        |                          | Brooke Army Medical Center   |         |           |
| Key Words:  | Bladder surface mucin<br>Transitional cell carcinoma |                          | Associate Investigators:<br>C. Ritchie Spence, M.D., COL, MC<br>William Gregory, SP5 |         |           |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: \$1,532                   | Periodic Review Results: |  |         |           |
| Objectives: To determine if presence of bladder surface mucin and/or artificial reconstitution thereof prevents implantation of transitional cell carcinoma of the bladder. |  |                          |  |         |           |

Technical Approach: Animals received intravesical methylnitrosourea to remove bladder surface mucin. Tumor cells were then instilled after preparatory vesical washings with either saline (control) or heparin (to reconstitute the mucin layer).

Progress: Heparin reconstitution was unable to significantly reduce tumor implantation in animals receiving significant intravesical urothelial trauma (with MNU). However, the heparin reconstitution decreased tumor implantation rates in animals with less significant urothelial trauma, secondary to simple bladder distention.

# Detail Summary Sheet

|  |   |                          |   |         |           |
|--|---|--------------------------|---|---------|-----------|
| Date:  | 15 Nov 83                                   | Proj No:                 | C-14-83   | Status: | Completed |
| TITLE:   |   |                          |   |         |           |
| A Comparative Study of the Effect of Two Rates of Infusion of Protamine Sulfate on the Cardiovascular System of Patients Undergoing Cardiopulmonary Bypass |   |                          |   |         |           |
| Start Date   | 6 Jan 83                                    | Est Comp Date:           |   |         |           |
| Principal Investigator   | Alan Rastrelli, M.D., CPT, MC               |                          | Facility  |         |           |
| Dept/Sec   | Department of Surgery/Anesthesiology        |                          | Brooke Army Medical Center  |         |           |
| Key Words:   | Protamine Sulfate<br>Cardiopulmonary Bypass |                          | Associate Investigators:<br>Thomas Shaw, D.O., CPT, MC<br>James B. Peake, M.D., COL, MC |         |           |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:                  | Periodic Review Results: |   |         |           |

Objective: To determine the hemodynamic effects of protamine sulfate infusion after cardiopulmonary bypass and to compare these effects at two different rates of infusion.

Technical Approach: Fifteen patients undergoing elective coronary artery bypass graft surgery were studied. Patients with other significant organ system diseases were excluded. The patients were randomly assigned to one of two groups. In eight patients protamine sulfate was infused at a constant rate over 90 seconds and in seven patients protamine sulfate was infused constantly over five minutes.

Progress: Analysis of the average responses revealed no significant changes in MAP, HR, PCWP, CPP in both groups. A statistically ( $p < .05$ ) significant change in CI between the two groups was noted at the 2, 5, and 10 minute time intervals, with the greatest change occurring at the 2 minute time interval. The changes in SVR were statistically different ( $p < .05$ ) between the two groups at time intervals 2, 5 and 10 minute and correlate inversely with changes in CI such that as the CI rose, the SVR decreased.

Following infusion of the protamine sulfate, there was a statistically significant difference in the PAPs at the 2 minute time interval with values returning towards control within 5-10 minutes. This statistically significant difference in PAPs was accompanied by significant parallel changes in PVR between the two groups.

C-14-83 (continued)

Conclusions: Our findings do not confirm previous observations that MAP frequently decreased with protamine infusion. Our patient population consistently maintained their MAP close to control values. The decrease in SVR occurring within 2 minutes after protamine sulfate infusion in Group I was associated with an increase in CI, maintaining the MAP and CPP near control levels. In Group II, the rise in SVR was associated with a decrease in CI, but also maintaining MAP and CPP near control levels. Thus it appears that the peripheral vasodilatation that occurs with rapid protamine sulfate infusion can be compensated for by increasing CO to maintain the MAP in those patients with healthy myocardiums.

# Detail Summary Sheet

Date: 3 Oct 83 Proj No: C-32-83 Status: Completed

## TITLE:

Adenocarcinoma of the Prostate - Results of Routine Urologic Screening

|                                |                            |                                  |
|--------------------------------|----------------------------|----------------------------------|
| Start Date                     | 19 Apr 83                  | Est Comp Date:                   |
| Principal Investigator         |                            | Facility                         |
| Ian M. Thompson, M.D., CPT, MC |                            | Brooke Army Medical Center       |
| Dept/Sec                       |                            | Associate Investigators:         |
| Department of Surgery/Urology  |                            | Joseph J. Ernst, M.D., CPT, MC   |
| Key Words:                     |                            | C. Ritchie Spence, M.D., COL, MC |
| Adenocarcinoma                 |                            |                                  |
| Prostate                       |                            |                                  |
| Accumulative MEDCASE Cost:     | Est Accumulative OMA Cost: | Periodic Review Results:         |

Objective: Retrospective analysis of the Urologic portion of the Health Screening Clinic will determine the yield of routine urologic examination of asymptomatic males over the age of 40 with specific attention to incidence of adenocarcinoma of the prostate.

Technical Approach: The charts of 2005 men who participated in routine urologic screening examinations during the period January 1979 to January 1983 were randomly selected and reviewed. All patients had previously undergone a complete physical examination with the exception of rectal examination by the screening physician. All participating patients were then referred to the Urology Service.

Routine urologic examinations included a complete urologic history. Physical examination of the abdomen, genitalia and digital-rectal examination of the prostate were then performed. Finally, a urinalysis was performed. Further diagnostic and/or therapeutic work was performed as dictated.

Progress: Microscopic hematuria was noted in 85 men but evaluation revealed a single vesical neoplasm. Digital-rectal examination was used to screen for adenocarcinoma of the prostate. Sixty-five nodules were detected of which 17 proved to be adenocarcinoma. Clinical staging revealed no evidence of metastases in all but two patients. Digital-rectal examination proved to be an insensitive screening device and the use of adjunct screening tools is suggested.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-35-83 Status: Ongoing  
 TITLE:

Cromolyn Sodium 4% Treatment for Vernal Conjunctivitis.

|  |  |
|--|--|
| Start Date 6 May 83                                  | Est Comp Date: May 85                  |
| Principal Investigator<br>Donald Bode, M.D., COL, MC | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department of Surgery/Ophthalmology      | Associate Investigators:               |
| Key Words:<br>Vernal conjunctivitis                  |  |
| Accumulative MEDCASE Cost:                           | Est Accumulative OMA Cost:             |
|  | Periodic Review Results:               |

Objective: To give relief of troublesome itching due to vernal conjunctivitis when conventional treatment has failed.

Technical Approach: The protocol of Fison Corporation will be used to treat for vernal conjunctivitis. Currently we have begun to enroll one patient in the study. Treatment has not yet begun.

Progress: None.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-36-83 Status: Ongoing

TITLE: Evaluation of the Boston Lens<sup>R</sup> and Supporting Solutions

|                        |  |                          |                            |
|------------------------|--|--------------------------|----------------------------|
| Start Date             | 6 May 83                               | Est Comp Date:           | May 84                     |
| Principal Investigator | Kenneth D. Gallinger, O.D., CPT, MSC   | Facility                 | Brooke Army Medical Center |
| Dept/Sec               | Department of Surgery/Optomtry Section | Associate Investigators: | Optometry Staff            |
| Key Words:             | Boston Lens                            |                          |                            |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine the safety and effectiveness of the Boston Lens<sup>R</sup> Contact Lens and supporting solutions.

Technical Approach: A variety of eyes have been evaluated as to efficacy of wearing the Boston lens to correct visual acuity, provide comfort, and provide an acceptable physiological fit of the eye.

Design of the lenses varies dramatically but typically follows designs of other rigid contact lens.

Progress: Evaluation has revealed that the lens is a safe, effective type of rigid contact lens. The basic premise of the manufacturer that the O<sub>2</sub> permeability is greater than with other lenses and, therefore, improves corneal physiology seems to hold true.

No corneal physiology problems have been noted. The primary problem encountered is drying of the anterior surface of the lens causing increased lid irritations. In some cases this is overcome using additional cleansing/wetting solutions throughout the day. Occasionally the patient discontinues the lenses for this reason. This problem exists in spite of a (company claimed) higher wetting angle.



# Detail Summary Sheet

Date: 15 Nov 83      Proj No: C-44-83      Status: Terminated

**TITLE:**

The Effect of Indomethacin on Postobstructive Diverticulis

|                                |           |                            |
|--------------------------------|-----------|----------------------------|
| Start Date                     | 17 May 83 | Est Comp Date:             |
| Principal Investigator         |           | Facility                   |
| Joseph J. Ernst, M.D., CPT, MC |           | Brooke Army Medical Center |
| Dept/Sec                       |           | Associate Investigators:   |
| Department of Surgery/Urology  |           |                            |
| Key Words:                     |           |                            |

|                            |                                  |                          |
|----------------------------|----------------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: \$201 | Periodic Review Results: |
|----------------------------|----------------------------------|--------------------------|

Objective: To determine the ability of Indomethacin to reduce the natriuresis and diuresis following release of bilateral ureteral occlusions.

Technical Approach: Using four rats, an attempt was made at ureteral ligation followed by ureteral catheterization to measure urine output. The former was not difficult, but catheterization proved quite different. Furthermore, urine output was unpredictable because of variations in unmeasured parameters (i.e., blood pressure, pulse). Because of these difficulties, the study was terminated.

Progress: As indicated above, the experiment was terminated due to technical difficulties.

# Detail Summary Sheet

|  |                                       |                          |  |         |           |
|--|---------------------------------------|--------------------------|--|---------|-----------|
| Date:  | 15 Nov 83                             | Proj No:                 | C-46-83  | Status: | Completed |
| TITLE:   |                                       |                          |  |         |           |
| Effect of Glucan on Immune-Mediated Inhibition of Transitional Cell Carcinoma Growth in the Murine Model                 |                                       |                          |  |         |           |
| Start Date   | 17 May 83                             | Est Comp Date:           |  |         |           |
| Principal Investigator   | Ian M. Thompson, M.D., CPT, MC        |                          | Facility   |         |           |
| Dept/Sec   | Department of Surgery/Urology         |                          | Brooke Army Medical Center   |         |           |
| Key Words:   | Transitional cell carcinoma<br>Glucan |                          | Associate Investigators:<br>C. Ritchie Spence, M.D., COL, MC<br>Ralph Ortiz, M.D., CPT, MC |         |           |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:            | Periodic Review Results: |  |         |           |
| Objective: To determine if glucan can inhibit and/or prevent growth of surgically-implanted transitional cell carcinoma. |                                       |                          |  |         |           |

Technical Approach: The study compared intravenous glucan versus intraperitoneal cytophosphamide in controlling growth of transitional cell tumor transplants in murine thighs.

Progress: Cytoxan is extremely useful in low bulk tumors and reduces animal mortality in the presence of tumor load. Cytoxan does not significantly reduce tumor growth rate in the presence of large tumor burden.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-52-83 Status: Ongoing

## TITLE:

Effect of 1/4% Phenylephrine Nose Drops on Otitis Media and Serous Otitis

|  |  |
|--|--|
| Start Date: 16 Jun 83                                  | Est Comp Date: Jun 84                                    |
| Principal Investigator<br>David L. Webb, M.D., MAJ, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Surgery/Otolaryngology       | Associate Investigators:<br>Terry E. Pick, M.D., LTC, MC |
| Key Words:<br>Otitis media<br>Serous otitis            |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To test the effect of phenylephrine nose drops on the course of otitis media and serous otitis.

Technical Approach: two hundred patients, ages 3-8 years, with acute onset otitis media or serous otitis, will be included in the study. All patients will receive antibiotic therapy. Patients not allergic to penicillin will receive Amoxacillin, and those allergic to penicillin will receive Septra. Patients assigned to Group A will receive 1/4% phenylephrine nose drops four times a day for two weeks. Patients assigned to Group B will receive a saline nose drop solution prepared by the pharmacy four times a day for two weeks. If at the end of two weeks the tympanogram shows no evidence of clearing, the code will be broken and another form of therapy instituted.

Progress: Due to extensive TDY assignments of the principal investigator, the clinical portion of this study has not begun.

# Detail Summary Sheet

|  |                                    |                          |                            |                              |         |
|--|------------------------------------|--------------------------|----------------------------|------------------------------|---------|
| Date:  | 15 Nov 83                          | Proj No:                 | C-53-83                    | Status:                      | Ongoing |
| TITLE:<br>Occupational History and Low Back Problems   |                                    |                          |                            |                              |         |
| Start Date   | 16 Jun 83                          | Est Comp Date:           | Jun 84                     |                              |         |
| Principal Investigator   | Stephen E. Piwinski, M.D., CPT, MC |                          | Facility                   | Brooke Army Medical Center   |         |
| Dept/Sec   | Department of Surgery/Orthopaedics |                          | Associate Investigators:   | Donald Gordon, M.D., LTC, MC |         |
| Key Words:   | Low back problems.                 |                          | R. Williams, M.D., COL, MC |                              |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:         | Periodic Review Results: |                            |                              |         |
| Objectives: To retrospectively examined occupational history of patients with selected diagnoses of low back problems. |                                    |                          |                            |                              |         |

Technical Approach; Participants will be selected by definite diagnostic and social criteria and will then be questioned concerning their occupational history. Occupations and hobbies of interest include heavy equipment operators, motorcyclists, aviators, armored vehicle crew members and parachutists.

Progress: Survey questionnaires have been accumulated but have not been evaluated.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-54-83 Status: Ongoing

## TITLE:

Plastafil Carbon-Fiber Implant Study

|                                    |                  |                            |        |
|------------------------------------|------------------|----------------------------|--------|
| Start Date                         | 8 Jul 83         | Est Comp Date:             | Dec 85 |
| Principal Investigator             |                  | Facility                   |        |
| Keith L. Markey, M.D., LTC, MC     |                  | Brooke Army Medical Center |        |
| Dept/Sec                           |                  | Associate Investigators:   |        |
| Department of Surgery/Orthopaedics |                  |                            |        |
| Key Words:                         |                  |                            |        |
| Anterior cruciate                  |                  |                            |        |
| Carbon fiber                       |                  |                            |        |
| Accumulative MEDCASE               | Est Accumulative | Periodic                   |        |
| Cost:                              | OMA Cost:        | Review Results:            |        |

Objectives: To determine the efficacy and safety of the Plastafil Carbon-Fiber Bioprosthesis in the surgical treatment of acute and chronic knee-ligament injuries involving the anterior cruciate ligament, with or without injuries to the medial collateral ligament, lateral collateral ligament or the posterior cruciate ligament.

Technical Approach: Total number of patients enrolled in this study in FY 83 is nine with four receiving carbon fiber, five receiving standard treatment. Military members and dependents are enrolled in the program as volunteers to study the efficacy of the investigational device, carbon fiber bioprosthesis for the anterior cruciate ligament. They are randomly selected for this device in comparison to standard therapy. The individual does not choose the method of treatment. Acute and chronic injuries are taken. In the chronic injuries, knee strength, agility, and performance are assessed preoperatively as well as the patient information sheet. In the postoperative evaluations at 3, 6, 9 and 12 months, these same parameters are re-evaluated.

Progress: As projected, approximately one patient is entering the program per week. There have been no adverse reactions to the investigational device reported to date. There has been one early failure of the device.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-56-83 Status: Ongoing

## TITLE:

A Clinical Study Comparing the Efficacy of Fenoprofen Calcium, Phenylbutazone, and Placebo in the Treatment of Acute Soft Tissue Injuries

|                                    |          |                                |        |
|------------------------------------|----------|--------------------------------|--------|
| Start Date                         | 8 Jul 83 | Est Comp Date:                 | Dec 83 |
| Principal Investigator             |          | Facility                       |        |
| Keith L. Markey, M.D., LTC, MC     |          | Brooke Army Medical Center     |        |
| Dept/Sec                           |          | Associate Investigators:       |        |
| Department of Surgery/Orthopaedics |          | Lydia A. Manuel, M.D., CPT, MC |        |
| Key Words:                         |          | Van E. Wahlgren, M.D., CPT, MC |        |
| Fenoprofen calcium                 |          |                                |        |
| Acute soft tissue injuries         |          |                                |        |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To compare the efficacy of Fenoprofen Calcium enteric coated, phenylbutazone, and placebo using patient-selected doses as anti-inflammatory and analgesic agents in the treatment of inflammatory soft tissue injuries.

Technical Approach: The patients are referred to the Orthopaedic Clinic from Troop Medical Clinic and Emergency Room with acute injuries. After physical examination, they undergo a double blind therapy treatment. Significant difficulty has been experienced in obtaining compliance with the treatment regimes and return for follow-up care from active duty personnel as their class and duty obligations preclude them from participation. Approximately 20 people have been entered in the study of which ten are valid subjects.

Progress: Patient accrual has been slow. Further expansion into different primary care treatment areas may be necessary.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-57-83 Status: Completed

## TITLE:

Circulatory Responses to Laryngoscopy with Miller or MacIntosh Blades

|                            |   |  |
|----------------------------|---|--|
| Start Date                 | 8 Jul 83  | Est Comp Date:   |
| Principal Investigator     | Timothy J. Norris, M.D., CPT, MC                | Facility   |
| Dept/Sec                   | Department of Surgery/Anesthesiology            | Brooke Army Medical Center                                     |
| Key Words:                 | Laryngoscopy<br>Miller Blade<br>MacIntosh Blade | Associate Investigators:<br>Curtis L. Baysinger, M.D., CPT, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:                      | Periodic Review Results:                                       |

Objective: To quantitate the heart rate and blood pressure responses to laryngoscopy by examining the impact of different laryngoscopic techniques and laryngoscope blades on the response.

Technical Approach: Thirty-three patients were entered on the study; however, three were dropped secondary to deviations from the protocol induction sequence. A protocol premed and induction sequence was utilized for all patients. Heart rate and blood pressure responses were measured during specific time intervals during the induction sequence.

Progress: An adequate patient population has been sampled, and the data procurement has been completed. There appears to be no significant differences on heart rate and blood pressure among the three laryngoscopic techniques studied. No adverse effects of physical injuries were sustained by any protocol participant.

# Detail Summary Sheet

|   |                                  |                          |         |         |         |
|---|----------------------------------|--------------------------|---------|---------|---------|
| Date:   | 15 Nov 83                        | Proj No:                 | C-61-83 | Status: | Ongoing |
| TITLE:  |                                  |                          |         |         |         |
| Impact of the Unilateral Ureteral Obstruction on Renal Excretion of Calcium and Phosphate   |                                  |                          |         |         |         |
| Start Date  | 10 Aug 83                        | Est Comp Date:           |         |         |         |
| Principal Investigator  | Facility                         |                          |         |         |         |
| Ian M. Thompson, Jr., M.D., CPT, MC   | Brooke Army Medical Center       |                          |         |         |         |
| Dept/Sec  | Associate Investigators:         |                          |         |         |         |
| Department of Surgery/Urology   | Joseph J. Ernst, M.D., CPT, MC   |                          |         |         |         |
| Key Words:  | C. Ritchie Spence, M.D., COL, MC |                          |         |         |         |
| Ureteral obstruction  | Edward J. Shumski, M.D., LTC, MC |                          |         |         |         |
| Calculi   |                                  |                          |         |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:       | Periodic Review Results: |         |         |         |
| Objective: To determine whether metabolic evaluation can be performed in the clinical setting on patients with unilaterally obstructing ureteral calculi. |                                  |                          |         |         |         |

Technical Approach: Comparison of total renal clearance of calcium, phosphate, and creatinine in animals undergoing unilateral ureteral occlusion versus animals undergoing sham operations.

Progress: None. Metabolic cages are a basic requirement of the study. These have been ordered but not received. The study cannot commence until the cages arrive.



# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-62-83 Status: Ongoing

TITLE:  
Intravitreal Injection of Beta-Lactam Antibiotics

|                                     |                            |                            |        |
|-------------------------------------|----------------------------|----------------------------|--------|
| Start Date                          | 10 Aug 83                  | Est Comp Date:             | Aug 84 |
| Principal Investigator              |                            | Facility                   |        |
| Mary A. O'Hara, M.D., CPT, MC       |                            | Brooke Army Medical Center |        |
| Dept/Sec                            |                            | Associate Investigators:   |        |
| Department of Surgery/Ophthalmology |                            | Donald Bode, M.D., COL, MC |        |
| Key Words:                          |                            |                            |        |
| Beta-lactam antibiotics             |                            |                            |        |
| Accumulative MEDCASE Cost:          | Est Accumulative OMA Cost: | Periodic Review Results:   |        |

Objective: To determine the toxicity of two beta-lactam antibiotics when administered intravitreally in rabbits.

Technical Approach: Inject rabbits with a beta-lactam antibiotic in increasing doses to measure the toxicity of the antibiotic to the eye.

Progress: The rabbits have been received. Injections will begin in the near future.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-63-83 Status: Ongoing

## TITLE:

Dose-Response Relationship of Cyclophosphamide in Murine Transitional Cell Carcinoma

|   |  |
|---|--|
| Start Date 10 Aug 83  | Est Comp Date:   |
| Principal Investigator<br>Ian M. Thompson, Jr., M.D., CPT, MC | Facility<br>Brooke Army Medical Center                               |
| Dept/Sec<br>Department of Surgery/Urology                     | Associate Investigators:<br>Donald Lamm., M.D.                       |
| Key Words:<br>Carcinoma, transitional cell                    | Edward J. Shumski, M.D., LTC, MC<br>C. Ritchie Spence, M.D., COL, MC |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine if cyclophosphamide can prevent tumor growth in doses in which it has been previously demonstrated that no agents effectively inhibit growth of murine transitional cell carcinoma.

Technical Approach: a comparison of the cytotoxic effects of a standard dose of cyclophosphamide for control of  $10^4$ ,  $10^5$ , and  $10^6$  tumor dose.

Progress: The study will begin as soon as the animals are received.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-71-83 Status: Ongoing

## TITLE:

Measurement of Myocardial Oxygen Consumption in Various Modes of Partial Left Heart Bypass

|  |  |
|--|--|
| Start Date 15 Nov 83   | Est Comp Date:   |
| Principal Investigator<br>David J. Cohen, M.D., MAJ, MC      | Facility<br>Brooke Army Medical Center   |
| Dept/Sec<br>Department of Surgery/Cardiothoracic             | Associate Investigators:<br>James B. Peake, M.D., COL, MC<br>Robert L. Treasure, M.D., COL, MC |
| Key Words:<br>Partial left heart bypass<br>Myocardial oxygen |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To develop a method of measuring  $MVO_2$  in a chronic animal preparation.

To utilize this model to assess the effectiveness of various forms of left heart bypass.

Technical Approach: Animals will be anesthetized using pentothal. Following placement of the endotracheal tube and necessary catheters, coronary sinus flow, coronary sinus  $O_2$  content and femoral artery  $O_2$  content will be measured. Coronary sinus flow should approximate left coronary artery flow and they should vary proportionally. Left ventricular myocardial oxygen consumption will thus be calculated using  $A-VO_2$  difference across the heart multiplied by coronary sinus flow.

Myocardial oxygen consumption will be measured baseline and then with left ventricular-to-aortic partial bypass and left atrial-to-aortic bypass. Each 15 minutes, the animal will be switched to a different mode of bypass in randomized block fashion and after 15 minutes equilibration time, the  $MVO_2$  will be measured. Three sets of data will be obtained for each mode of bypass.

Progress: This is a new study.

# Detail Summary Sheet

|   |                                  |                          |                          |   |         |
|---|----------------------------------|--------------------------|--------------------------|---|---------|
| Date:   | 15 Nov 83                        | Proj No:                 | C-74-83                  | Status:   | Ongoing |
| TITLE:  |                                  |                          |                          |   |         |
| Coagulum Pyelolithotomy Using Cryoprecipitate with or without the use of Thrombin |                                  |                          |                          |   |         |
| Start Date  | 30 Sep 83                        | Est Comp Date:           | Nov 83                   |   |         |
| Principal Investigator  | Kenneth R. Bryant, M.D., CPT, MC |                          | Facility                 | Brooke Army Medical Center  |         |
| Dept/Sec  | Department of Surgery/Urology    |                          | Associate Investigators: | John C. Norbeck, M.D., MAJ, MC                                    |         |
| Key Words:  | Pyelolithotomy<br>Thrombin       |                          |                          | Rene Sepulveda, M.D., MAJ, MC<br>C. Ritchie Spence, M.D., COL, MC |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:       | Periodic Review Results: |                          |   |         |

Objective: To show that cryoprecipitate injected into the renal pelvis of an adult pig will produce a coagulum with a tensile strength comparable to a coagulum produced by mixing cryoprecipitate and bovine thrombin in a 25:3 ratio.

Technical Approach: Ten pigs will be obtained and will be well hydrated. Each kidney will be exposed through a midline transabdominal incision. The renal pelvis of each kidney will be canulated and the volumes measured. The right renal pelvis will be filled with enough cryoprecipitate to equal the measured volume. The left renal pelvis will be filled with a mixture of cryoprecipitate, bovine thrombin and 10% calcium chloride. After five minutes, the renal pelvis will be quickly dissected and the coagulum extracted. A standard core of coagulum will be taken from the center of each specimen, and the tensile strength of each core measured using a hanging scale.

Progress: This is a new study.

# Detail Summary Sheet

|  |                                     |                          |   |         |         |
|--|-------------------------------------|--------------------------|---|---------|---------|
| Date:  | 15 Nov 83                           | Proj No:                 | C-75-83   | Status: | Ongoing |
| TITLE:   |                                     |                          |   |         |         |
| The Preservation of Cellular Architecture by Verapamil During Renal Artery Occlusion |                                     |                          |   |         |         |
| Start Date   | 30 Sep 83                           | Est Comp Date:           | Nov 83  |         |         |
| Principal Investigator   | Joseph J. Ernst, M.D., CPT, MC      |                          | Facility  |         |         |
| Dept/Sec   | Department of Surgery/Urology       |                          | Brooke Army Medical Center  |         |         |
| Key Words:   | Verapamil<br>Renal artery occlusion |                          | Associate Investigators:  |         |         |
|  |                                     |                          | Ian M. Thompson, M.D., CPT, MC<br>Edward Shumski, M.D., LTC, MC<br>C. Ritchie Spence, M.D., COL, MC |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:          | Periodic Review Results: |   |         |         |

Objective: To determine the ability of Verapamil to prevent ischemic changes in renal histology and intracellular architecture following renal artery occlusion in rats.

Technical Approach: Eighteen rats will be studied. Animals will be divided into two groups. In the control group, unilateral renal artery occlusion will be performed under pentobarbital anesthesia. Occlusion will be accomplished through a midline incision. After release of the occlusion, the incision will be closed and the animals allowed to recover. In the experimental group, the surgical procedure will be the same with the exception that 15 minutes prior to renal artery occlusion, Verapamil hydrochloride will be administered as a bolus over a two minute period through the femoral vein. One animal from each group will be sacrificed on days 2, 5, and 7. Two animals from each group will be sacrificed on days 14, 21, and 28. Both kidneys will be excised and placed in formalin and cold glutaraldehyde for light and electron microscopy, respectively.

Progress: This is a new study.

# Detail Summary Sheet

|   |   |                          |   |         |         |
|---|---|--------------------------|---|---------|---------|
| Date:   | 15 Nov 83                                     | Proj No:                 | C-81-83   | Status: | Ongoing |
| TITLE:  |   |                          |   |         |         |
| Chronic Administration of Nifedipine and the Cardiovascular Responses to High-Dose Fentanyl Anesthesia and Coronary Artery Bypass Grafting in Man |   |                          |   |         |         |
| Start Date  | 30 Sep 83                                     | Est Comp Date: Jan 84    |   |         |         |
| Principal Investigator  | John T. Caskey, M.D., CPT, MC                 |                          | Facility  |         |         |
| Dept/Sec  | Department of Surgery/Anesthesiology          |                          | Brooke Army Medical Center  |         |         |
| Key Words:  | Coronary artery bypass grafting<br>Nifedipine |                          | Associate Investigators:<br>Curtis L. Baysinger, M.D., CPT, MC<br>James B. Peake, M.D., COL, MC |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:                    | Periodic Review Results: |   |         |         |

Objective: To investigate the cardiovascular effects of the prior administration of nifedipine in patients anesthetized with fentanyl-diazepam-pancuronium-oxygen during coronary artery bypass surgery.

Technical Approach: Forty-four male patients who will undergo coronary artery bypass graft surgery. Thirty-three patients taking nifedipine on a chronic basis will be randomly assigned to three groups of eleven. Eleven patients not taking nifedipine will serve as a control group. Group 1 will not receive any nifedipine for 24-36 hours prior to surgery. Group 2 will receive one-half their usual morning dose on the day of surgery, and Group 3 will receive their full morning dose on the day of surgery.

Hemodynamic, fluid and coagulation parameters will be recorded. The parameters will be compared between groups by the non-paired t test and compared between times for the same group by the non-paired t test.

Progress: This is a new study.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-33-82 Status: Ongoing

## TITLE:

Evaluation of Radiation Exposure to Personnel During Cardiac Catheterization

|                                 |                            |                            |        |
|---------------------------------|----------------------------|----------------------------|--------|
| Start Date                      | 18 May 82                  | Est Comp Date:             | Jan 84 |
| Principal Investigator          |                            | Facility                   |        |
| Robert N. Cherry, Jr., MAJ, MSC |                            | Brooke Army Medical Center |        |
| Dept/Sec                        |                            | Associate Investigators:   |        |
| Medical Physics Service         |                            |                            |        |
| Key Words:                      |                            |                            |        |
| Radiation exposure              |                            |                            |        |
| Cardiac catheterization         |                            |                            |        |
| Accumulative MEDCASE Cost:      | Est Accumulative OMA Cost: | Periodic Review Results:   |        |

Objective: To assess x-ray exposure levels of personnel during cardiac catheterizations, particularly exposures to the lens of the eye and the thyroid which are the radiosensitive organs of interest.

Technical Approach: The mensuration of the x-ray exposure levels is accomplished by placing small solid state detectors (LIF) on the foreheads and at the sternal notch of physicians and technicians performing the cardiac catheterizations. Additional data is obtained from film badge exposures and mechanical timers placed in the laboratory.

Progress: Part of study involving use of thermoluminescent dosimeters has been completed. In April, a new shielding device was installed. Its effects in reducing head-and-neck exposure are now being assessed.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-21-82 Status: Ongoing

## TITLE:

A Predictive Model for Estimating the Response to the Army Physical Fitness and Weight Control Program

Start Date 16 Feb 82

Est Comp Date: Nov 83

Principal Investigator

Facility

Kenneth D. James, MAJ, AMSC

Brooke Army Medical Center

Dept/Sec

Associate Investigators:

Food Service Division/Clinical Dietetics

Key Words:

Weight control

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost:

Review Results:

Objectives: To determine if overweight but generally healthy soldiers participating in a mandatory weight reduction program lose weight at the same rate and degree as matched general clinic patients desiring weight loss for cosmetic and/or health reasons.

To evaluate and identify factors which will predict compliance with and results of the weight control program as applied to individual soldiers.

To identify and evaluate factors within the administration of the program which may be indicative of successful compliance with and completion of the program by individual soldiers.

Technical Approach: Patients were selected, questionnaires administered and monthly follow-up questionnaires administered.

Progress: Data collection completed and presently being analyzed.



# Detail Summary Sheet

|   |  |                          |
|---|--|--------------------------|
| Date: 15 Nov 83   | Proj No: C-31-83                       | Status: Completed        |
| TITLE: A Comparison of Handling Errors During Facilitation of Head Control in High Risk Infants by Parents Exposed to Different Strategies for Learning a Motor Skill |  |                          |
| Start Date 19 Apr 83  | Est Comp Date:                         |                          |
| Principal Investigator<br>Margaret J. Satterfield, CPT, AMSC  | Facility<br>Brooke Army Medical Center |                          |
| Dept/Sec<br>Physical Medicine/Physical Therapy Section  | Associate Investigators:               |                          |
| Key Words:<br>High risk infant  |  |                          |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:             | Periodic Review Results: |

Objective: To determine which learning strategies are most conducive for adults to learn a novel, relevant psychomotor skill or the effect that such factors as age and parenting experience have on a mother's ability to competently handle a high risk infant.

Technical Approach: Seventy-five high risk neonates admitted to the intensive care unit were randomly assigned to one of three groups. Each group was then randomly preassigned one of three experimental treatments: no intervention, demonstration only, or demonstration-simulation. Each mother was assigned to the randomized group that contained her infant. Mothers in the demonstration group were shown handling techniques used by neurodevelopmental therapists to facilitate the infant's head control in prone, supine, and sitting. Mothers in the demonstration-simulation group were shown the same techniques and were allowed to practice them on a doll that was modified to simulate the muscle tone of high risk infants. Mothers in the control group were asked to show the physical therapist how they would position their infant to individually and then simultaneously stimulate the muscles in front of and behind the infant's neck. Using predetermined criteria, the same physical therapist graded each element of every mother's performance.

Progress: The results indicated that mothers in guided learning groups displayed better motor performances than show in the discovery group. However, in the demonstration-simulation group, the mothers actual performances were no better than their simulated performances. Mothers less than 25 years of age had significantly poorer performances when compared to mothers equal to or greater than 25 years of age. In contrast, mothers with parenting experience performed no better than mothers without experience.

# Detail Summary Sheet

|   |                                 |                          |                          |                              |         |
|---|---------------------------------|--------------------------|--------------------------|------------------------------|---------|
| Date:   | 16 Nov 83                       | Proj No:                 | C-85-83                  | Status:                      | Ongoing |
| TITLE:  |                                 |                          |                          |                              |         |
| A Comparison of the Hold-relax and Fluori-methane Spray Procedures in Increasing Hamstring Flexibility  |                                 |                          |                          |                              |         |
| Start Date  | 30 Sep 83                       | Est Comp Date:           | Aug 84                   |                              |         |
| Principal Investigator  | Francis J. Pottenger, 2LT, AMSC |                          | Facility                 | Academy of Health Sciences   |         |
| Dept/Sec  | Physical Therapy Section        |                          | Associate Investigators: | Laurie C. Chapman, 2LT, AMSC |         |
| Key Words:  | Hamstring flexibility           |                          |                          |                              |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:      | Periodic Review Results: |                          |                              |         |
| Objective: To evaluate and compare two currently used therapeutic techniques to improve hamstring flexibility in a sample population of normal males. |                                 |                          |                          |                              |         |

Technical Approach: Participants will be randomly assigned to one of two programs. Group 1 will apply Fluori-methane to the skin and group 2 will perform a series of muscle movements and isometric contractions.

Progress: This is a new study.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: C-86-83 Status: Ongoing

## TITLE:

Comparison of Submximal versus Maximal Warm-ups on Isokinetic Tests

|                            |                            |                            |
|----------------------------|----------------------------|----------------------------|
| Start Date                 | 30 Sep 83                  | Est Comp Date: Ongoing     |
| Principal Investigator     |                            | Facility                   |
| M. Jane Hays, 2LT, AMSC    |                            | Academy of Health Sciences |
| Dept/Sec                   |                            | Associate Investigators:   |
| Physical Therapy Section   |                            |                            |
| Key Words:                 |                            |                            |
| Submaximal warm-up         |                            |                            |
| Maximal warm-up            |                            |                            |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results:   |

Objective: To determine what type of warm-up will produce the most accurate measurement of baseline performance.

Technical Approach: Participants in the study will receive an orientation on the Cybex II. Muscles of the quadriceps group will be measured. Both legs will be tested alternately using different types of warm-up contractions. Next a test of six maximal contractions consisting of rapid forceful straightening of the knee will be measured.

Progress: This is a new study.

# Detail Summary Sheet

|  |                            |                          |         |         |         |
|--|----------------------------|--------------------------|---------|---------|---------|
| Date:  | 16 Nov 83                  | Proj No:                 | C-87-83 | Status: | Ongoing |
| TITLE:   |                            |                          |         |         |         |
| The Effects of Gravity Guided Lumbar Traction on Intervertebral Dimensions in the Lumbar Spine                                   |                            |                          |         |         |         |
| Start Date   | 30 Sep 83                  | Est Comp Date:           | Ongoing |         |         |
| Principal Investigator   | Facility                   |                          |         |         |         |
| Michael D. Kane, 2LT, AMSC   | Academy of Health Sciences |                          |         |         |         |
| Dept/Sec   | Associate Investigators:   |                          |         |         |         |
| Physical Therapy Section   |                            |                          |         |         |         |
| Key Words:   |                            |                          |         |         |         |
| Lumbar spine   |                            |                          |         |         |         |
| Lumbar traction  |                            |                          |         |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |         |         |         |
| Objective: To determine whether gravity guided lumbar traction can produce measurable vertebral distraction at the lumbar spine. |                            |                          |         |         |         |

Technical Approach: Participants will undergo physical examination prior to entry on the study. Initial part of the experiment requires standing erect and lateral x-ray of the lower back obtained. They are then placed in the traction apparatus and remain upside-down for ten minutes following which another x-ray of the lower back is obtained.

Progress: This is a new study.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: C-88-83 Status: Ongoing

TITLE:

Analysis of a Method of Measuring Pelvic Tilt

|   |                               |  |
|---|-------------------------------|--|
| Start Date 30 Sep 83  |                               | Est Comp Date: Aug 84                  |
| Principal Investigator<br>Joanna M. Graziadei, 2LT, AMSC                    |                               | Facility<br>Academy of Health Sciences |
| Dept/Sec<br>Physical Therapy Section  |                               | Associate Investigators:               |
| Key Words:<br>Pelvic tilt   |                               |  |
| Accumulative MEDCASE<br>Cost:   | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results:            |
| Objective: To evaluate a proposed clinical method of measuring pelvic tilt. |                               |  |

Technical Approach: Participants in protocol C-87-83 will be asked to take part in this study. Following the initial x-ray, two points on the upper pelvis will be marked with a felt pen. Measurements will be taken with bowleg calipers (to measure the distance between the two points on the pelvis) and a modified yardstick (to measure the distance from the floor to the points on the pelvis).

Progress: This is a new study.

# Detail Summary Sheet

|   |                            |                          |                          |                            |         |
|---|----------------------------|--------------------------|--------------------------|----------------------------|---------|
| Date:   | 16 Nov 83                  | Proj No:                 | C-89-83                  | Status:                    | Ongoing |
| TITLE:  |                            |                          |                          |                            |         |
| A Comparative Analysis of the U.S. Army's Method for Determining Body Fat Content   |                            |                          |                          |                            |         |
| Start Date  | 30 Sep 83                  | Est Comp Date:           | Aug 84                   |                            |         |
| Principal Investigator  | Michael Sharr, 2LT, AMSC   |                          | Facility                 | Academy of Health Sciences |         |
| Dept/Sec  | Physical Therapy Section   |                          | Associate Investigators: |                            |         |
| Key Words:  | Body fat content           |                          |                          |                            |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: |                          |                            |         |
| Objective: To evaluate the predictive accuracy of the U.S. Army's method for determining per cent body fat recently established under AR 600-9. |                            |                          |                          |                            |         |

Technical Approach: Skinfold thickness and circumference measurements will be taken. Next, measurment of height, weight, body volume and residual lung volume will be taken. Then utilizing the Body Volumeter located at Brooks AFB School of Aerospace Medicine, the amount of water displacement will be measured.

Progress: This is a new study.

# Detail Summary Sheet

|  |                             |                             |                            |         |         |
|--|-----------------------------|-----------------------------|----------------------------|---------|---------|
| Date:  | 16 Nov 83                   | Proj No:                    | C-90-83                    | Status: | Ongoing |
| TITLE:   |                             |                             |                            |         |         |
| Comparison of Using Heat versus Heat and Cold During Stretching to Improve Flexibility                   |                             |                             |                            |         |         |
| Start Date   | 30 Sep 83                   | Est Comp Date:              | Aug 84                     |         |         |
| Principal Investigator   | Robert J. Bessen, 2LT, AMSC |                             | Facility                   |         |         |
| Dept/Sec   | Physical Therapy Section    |                             | Academy of Health Sciences |         |         |
| Key Words:   | Flexibility                 |                             | Associate Investigators:   |         |         |
|  |                             | Gregory P. Ernst, 2LT, AMSC |                            |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:  | Periodic Review Results:    |                            |         |         |
| Objective: To evaluate the effectiveness of using heat versus heat and cold during hamstring stretching. |                             |                             |                            |         |         |

Technical Approach: Each leg will be alterantely tested until a total of two tests is performed. During the treatment period, the subject will be sitting on a plinth which his back against a wall. The feet will be propped up on a foot stool and as many 2x4 wood blacks as are necessary to adjust the height to patient tolerance of hamstring stretch will be utilized. Both legs will be at the same height, giving equal stretch to each hambstring group.

A 10 minute ultrasound treatment will be applied to both thighs simultaneously. Following ultrasound, hydrocollator packs will be placed on both posterior thighs for 20 minutes. Next, the experimental thigh will receive a 10 minute ice massage. The control thigh will remain in a stretched position but will receive no treatment. Flexibility of the thighs will be measured in the same manner as initially.

Progress: This is a new study.

# Detail Summary Sheet

|  |  |                          |
|--|--|--------------------------|
| Date: 16 Nov 83  | Proj No: C-91-83                       | Status: Ongoing          |
| TITLE:<br>The Effect of Arthroscopic Debridement and Washout on the Degenerative Knee as Demonstrated on the Cybex II Isokinetic Dynamometer |  |                          |
| Start Date 30 Sep 83   | Est Comp Date: Aug 84                  |                          |
| Principal Investigator<br>Ann E. Matson, 2LT, AMSC   | Facility<br>Academy of Health Sciences |                          |
| Dept/Sec<br>Physical Therapy Section   | Associate Investigators:               |                          |
| Key Words:<br>Cybex II dynamometer   |  |                          |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:             | Periodic Review Results: |

Objective: To compare quadriceps strength pre- and postoperatively in patients with degenerative joint disease, having been treated with percutaneous arthroscopic debridement and washout using the Cybex II isokinetic dynamometer and the Cybex isokinetic dual channel recorder.

Technical Approach: Utilizing the Cybex II, isokinetic exercises will be performed and measurements taken. The study will be carried out in two sessions of approximately 15 minutes each. One testing session will be immediately prior to surgery and one will be during the week following surgery

The Cybex II isokinetic dynamometer and dual channel recorder provide the researcher with a strip-chart recording representing foot-pounds of torque produced throughout the range of motion. Percentage "strength" deficit will be calculated for the arthritic knee by comparing peak torque values produced at each speed to the uninvolved knee which will be considered to have a value of 100% or zero torque deficit.

Active range of motion will be measured in the standard manner using a long arm goniometer. Girth of the operative knee will be measured using a centimeter tape measure at the sites previously mentioned. These values will demonstrate when the criteria for the postoperative Cybex testing have been met.

Progress: This is a new study.



# Detail Summary Sheet

Date: 16 Nov 83 Proj No: C-92-83 Status: Ongoing

## TITLE:

The Influence of Warm Water Immersion on Muscle Tension as Measured by Electromyography in Hemiplegic Patients

|                            |                                |                          |   |
|----------------------------|--------------------------------|--------------------------|---|
| Start Date                 | 30 Sep 83                      | Est Comp Date:           | Ongoing   |
| Principal Investigator     | Karen A. Johnson, 2LT, AMSC    | Facility                 | Academy of Health Sciences                            |
| Dept/Sec                   | Physical Therapy Section       | Associate Investigators: | Bruce Reed, 2LT, AMSC<br>Connie J. Seymour, 2LT, AMSC |
| Key Words:                 | Electromyography<br>Hemiplegia |                          |   |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:     | Periodic Review Results: |   |

Objective: To evaluate the influence of warm water immersion on muscle tonus in hemiplegic patients.

Technical Approach: Hemiplegic patients will be randomly assigned to one of two groups; either a control group where no treatment is administered or an experimental group where the patient will receive treatment. The electrical activity within the involved upper extremity will be measured before and after treatment, or for the control group immediately before and after a 25 minute interval.

Participants will be taken to the treatment room and the involved arm immersed in the whirlpool. Prior to immersion, resting EMG and skin temperature will be monitored for one minute. Performance of the Fugl-Meyer Assessment will be monitored by observation and the BIOLAB 21 for three minutes. Surface electrodes, previously placed two centimeters apart and parallel to muscle fibers on the proximal ventral surface of the involved forearm, will then be removed and their location marked. The patient's involved forearm will then be immersed in water at a temperature of 95° F for 25 minutes. During the immersion of the affected arm, associated reactions will be monitored. Upon removal of the forearm from the whirlpool, resting EMG and skin temperature will again be measured for one minute. The subject will then perform the Fugl-Meyer Assessment for three minutes.

Progress: This is a new study.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: C-93-83 Status: Ongoing

## TITLE:

Eye Movement and Its Effect on Suboccipital Muscle Activity

|                            |                              |                          |                            |
|----------------------------|------------------------------|--------------------------|----------------------------|
| Start Date                 | 30 Sep 83                    | Est Comp Date:           | Aug 84                     |
| Principal Investigator     | Lawrence A. Bates, 2LT, AMSC | Facility                 | Academy of Health Sciences |
| Dept/Sec                   | Physical Therapy Section     | Associate Investigators: |                            |
| Key Words:                 | Suboccipital muscle          |                          |                            |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:   | Periodic Review Results: |                            |

Objective: To add to the existing body of knowledge in the area of neuro-muscular rehabilitation by showing a physiological link between eye movement and suboccipital muscle activity.

Technical Approach: Simultaneous ocular movement and muscle activity of the rectus capitus posterior major and obliquus capitus inferior muscles will be measured. An audiologist will oversee the ENG machinery and a physiatrist will oversee the use of the EMG equipment. Surface electrodes will be placed on the skin surrounding the right eye to measure eye movement. Four electrodes will be used (one above, one below, and one on either side of the right eye), and they will be pasted to the skin. Needle electrodes will be placed in the two muscles on the right side of the back of the neck.

The actual testing consists of looking to the right, then to the left, then up and then down. Next a series of lights will cross the visual field first from left to right, then right to left, then down to up and lastly, up to down. These will be repeated three times. Lastly, manual pressure will be applied to the eye in each of four areas; superiorly inferiorly, laterally, and mediatlly. Enough pressure will be applied to artificially induce a 15° eye displacement as read on the ENG. EMG activity will be recorded simultaneously.

Progress: This is a new study.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: C-94-83 Status: Ongoing

## TITLE:

Quadriceps Strength in Open Versus Closed Menisectomy

|                             |                            |                            |        |
|-----------------------------|----------------------------|----------------------------|--------|
| Start Date                  | 30 Sep 83                  | Est Comp Date:             | Aug 84 |
| Principal Investigator      |                            | Facility                   |        |
| Mary Adriene Orr, 2LT, AMSC |                            | Academy of Health Sciences |        |
| Dept/Sec                    |                            | Associate Investigators:   |        |
| Physical Therapy Section    |                            |                            |        |
| Key Words:                  |                            |                            |        |
| Quadriceps strength         |                            |                            |        |
| Meniscectomy                |                            |                            |        |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results:   |        |

Objective: To evaluate the two methods of surgical management of meniscal derangement as measured by patient performance on the Cybex II isokinetic exercise/testing unit.

Technical Approach: Range of motion will be measured with a long-arm goniometer. Circumferential measurements will be made at the mi-patellar site. The postoperative quadriceps strength will be collected and analyzed from the Cybex II isokinetic chart recorder.

Progress: This is a new study.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-1-78 Status: Terminated  
 TITLE:

Tetracycline-induced Ultraviolet Fluorescence of Pathologic Pulmonary  
 Tissues as Viewed Through the Fiberoptic Bronchoscope

|  |                                   |
|--|-----------------------------------|
| Start Date Oct 77  | Est Comp Date:                    |
| Principal Investigator<br>William W. Burgin, M.D., COL, MC | Facility<br>Darnall Army Hospital |
| Dept/Sec   | Associate Investigators:          |
| Key Words:<br>Fluorescence<br>Tetracycline                 |                                   |

|                               |                               |                             |
|-------------------------------|-------------------------------|-----------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: |
|-------------------------------|-------------------------------|-----------------------------|

Objective: To establish whether in vivo tetracycline labeling can be used to aid the endoscopist in locating pathologic pulmonary tissues when viewed through a fiberoptic bronchoscope incorporating an ultraviolet light source.

Technical Approach: None.

Progress: This project was never started because of technical and personnel problems.

# Detail Summary Sheet

Date: 15 Nov 83 Proj No: C-43-83 Status: Ongoing  
TITLE:

Comparison of Changes in Blood Pressure and Heart Rate with Metocurine and d-Tubocurarine

|   |   |
|---|---|
| Start Date 17 May 83                              | Est Comp Date: May 84   |
| Principal Investigator<br>Carolyn Craig, CPT, ANC | Facility<br>Darnall Army Hospital   |
| Dept/Sec<br>Department of Nursing/Anesthesiology  | Associate Investigators:<br>Alex House, CPT, ANC<br>John A. Whitfield, CPT, ANC |
| Key Words:<br>Metocurine<br>d-Tubocurarine        |   |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine the statistical difference and significance of changes in heart rate and mean arterial blood pressure that are attributable to the pharmacodynamics of Metocurine and d-Tubocurarine when extraneous variables of disease state, rate of injection, dose and metabolism, etc. are controlled.

Technical Approach: Random sampling of 28 ASA-I male and female subjects presenting for elective surgery below the diaphragm are given equipotent intubation doses of either Metocurine or d-Tubocurarine. Changes in heart rate and blood pressure changes are monitored, non-invasively, at 1, 3, and 5 minute intervals.

Progress: Thus far 10 subjects have been evaluated. Preliminary data suggest a favorable rate-pressure product with Metocurine versus Curare but data have not been statistically analyzed.

# Detail Summary Sheet

|   |                            |                                  |         |         |           |
|---|----------------------------|----------------------------------|---------|---------|-----------|
| Date:   | 15 Nov 83                  | Proj No:                         | C-47-83 | Status: | Completed |
| TITLE: A Comparison of the Incidence of Transient Bacteremias Following Prophylaxis with a Rubber Cup and Prophylactic Paste Compared to that Following Prophylaxis with the Propy Jet  |                            |                                  |         |         |           |
| Start Date  | 16 Jun 83                  | Est Comp Date:                   |         |         |           |
| Principal Investigator  |                            | Facility                         |         |         |           |
| Alan B. Bronstein, D.D., MAJ, DC  |                            | Darnall Army Hospital            |         |         |           |
| Dept/Sec  |                            | Associate Investigators:         |         |         |           |
| Department of Dentistry   |                            | A. Michael Krakow, D.D., LTC, DC |         |         |           |
| Key Words:  |                            |                                  |         |         |           |
| Bacteremia  |                            |                                  |         |         |           |
| Prophylaxis <sup>R</sup>  |                            |                                  |         |         |           |
| Prophy-Jet <sup>R</sup>   |                            |                                  |         |         |           |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results:         |         |         |           |
| Objective: To compare the incidence of transient bacteremias in patients receiving professional prophylaxis with a rubber cup and prophylactic paste with that found among patients treated with the Propy-Jet <sup>R</sup> . |                            |                                  |         |         |           |

Technical Approach: After passing selection criteria considering medical and gingival health, each subject randomly chose a patient number. Each patient number had assigned to it a side and sequence for prophylaxis with either rubber cup and paste or Propy Jet using a half mouth technique. After one side of the mouth was clean with one technique, a 5 ml blood sample was taken at chairside and aseptically inoculated into a culture medium. After a 20 minutes wait, the other side of the mouth was then cleaned using the prophylaxis method not yet used. A second blood sample was then taken. Both inoculates were then tested over a two week period for evidence of aerobic or anaerobic growth.

Progress: Two patients were found to have bacteremias following a half-mouth prophylaxis. The bacteremias occurred following the use of the Propy Jet. No bacteremias occurred following the rubber cup method. In one case of bacteremia, the Propy Jet was used first on one side of the mouth and the rubber cup was used second on the other side. In the second case the rubber cup was used first and the Propy Jet used second.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: C-48-83 Status: Ongoing

## TITLE:

An Evaluation of the Efficacy of Electroacupuncture in the Treatment of Temporomandibular Joint Pain

|                            |                                   |                          |  |
|----------------------------|-----------------------------------|--------------------------|--|
| Start Date                 | 16 Jun 83                         | Est Comp Date:           | Jan 84                                     |
| Principal Investigator     | Bradford W. Harper, D.D., MAJ, DC | Facility                 | Darnall Army Hospital                      |
| Dept/Sec                   | Department of Dentistry           | Associate Investigators: | Robert E. Hillis, D.D.S., M.D.,<br>COL, DC |
| Key Words:                 | Electroacupuncture<br>TMJ pain    |                          |  |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:        | Periodic Review Results: |  |

Objective: To determine the efficacy of electroacupuncture in the initial treatment of temporomandibular joint pain as compared to a standard initial treatment.

Technical Approach: Patients experiencing temporomandibular pain were separated into two treatment groups following an initial examination which incorporated objective and subjective criteria for quality and quantity of pain. One group was treated with a palliative regimen (aspirin, hot moist packs, soft diet, and limited opening) and one group with electrostimulation of acupuncture points L4, St6, Ex2 plus trigger points.

Progress: Eighteen patients have received examination, treatment, and post-treatment evaluation. Data is currently undergoing statistical analysis. Results appear to indicate that there is no difference between the two tested treatment modes. No adverse effects or physical injuries were sustained as a result of participation in the study.

# Detail Summary Sheet

|  |                                |                          |         |         |         |
|--|--------------------------------|--------------------------|---------|---------|---------|
| Date:  | 16 Nov 83                      | Proj No:                 | C-49-83 | Status: | Ongoing |
| TITLE:   |                                |                          |         |         |         |
| The Effect of the Periodontal Ligament Injection on Obtaining Adequate Local Anesthesia for Extraction of Erupted Mandibular Molars and Bicuspid |                                |                          |         |         |         |
| Start Date   | 16 Jun 83                      | Est Comp Date:           | Jan 84  |         |         |
| Principal Investigator   | Facility                       |                          |         |         |         |
| Michael W. Judah, D.D., MAJ, DC  | Darnall Army Hospital          |                          |         |         |         |
| Dept/Sec   | Associate Investigators:       |                          |         |         |         |
| Department of Dentistry  | Durwood E. Bach, D.D., MAJ, DC |                          |         |         |         |
| Key Words:   |                                |                          |         |         |         |
| Adequacy of anesthesia   |                                |                          |         |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:     | Periodic Review Results: |         |         |         |

Objectives: To evaluate the effect of the periodontal ligament injection in obtaining adequate anesthesia for extraction of erupted mandibular molars and bicuspid when using the Ligmaject\*\* syringe and 2% lidocaine with 1:100,000 epinephrine in a randomly selected population of male and female patients ranging in age from 12 to 60.

Technical Approach: Two methods of producing local anesthesia were used, the periodontal ligament injection and the more conventional nerve block injection method in which the patient receives and inferior alveolar, lingual and long buccal nerve block. These two methods of producing local anesthesia were then compared with respect to their relative effectiveness in obtaining adequacy of anesthesia for the removal of erupted mandibular molars and bicuspid.

Progress: Nineteen patients have been entered into the study. Due to non-availability of sufficient number of unilateral cases, one portion of the study may be dropped. Approximately 50% of the data collection has been completed.



# Detail Summary Sheet

Date: 16 Nov 83 Proj No: C-65-83 Status: Ongoing

## TITLE:

Perinatal Hyperviscosity

|  |                                   |
|--|-----------------------------------|
| Start Date 10 Aug 83   | Est Comp Date: Aug 84             |
| Principal Investigator<br>Jose' I. Gierbolini, M.D., MAJ, MC | Facility<br>Darnall Army Hospital |
| Dept/Sec<br>Department of Pediatrics                         | Associate Investigators:          |
| Key Words:<br>Hyperviscosity                                 |                                   |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To test the hypothesis that maternal and neonatal blood viscosities are correlated.

Technical Approach: A 3cc venous sample of blood will be obtained at the time of admission to the labor suite. Blood viscosity will be measured and microhematocrit will be determined. Following delivery, a 1.5 cc blood sample will be obtained for hematocrit and viscosity measurement.

Progress: No patients have been entered on the study.

# Detail Summary Sheet

|   |           |                            |                             |                          |           |
|---|-----------|----------------------------|-----------------------------|--------------------------|-----------|
| Date:   | 16 Nov 83 | Proj No:                   | C-39-82                     | Status:                  | Completed |
| TITLE:  |           |                            |                             |                          |           |
| Comparison of Electrosurgery and Surgical Blade Loops in the Removal of Inflammatory Papillary Hyperplasia  |           |                            |                             |                          |           |
| Start Date  |           |                            | 7 Jul 82                    |                          |           |
| Principal Investigator  |           |                            | Est Comp Date:              |                          |           |
| Furmon M. Gardner, D.D.S., LTC, DC  |           |                            | Facility                    |                          |           |
| Dept/Sec  |           |                            | Reynolds Army Hospital      |                          |           |
| Department of Dentistry   |           |                            | Associate Investigators:    |                          |           |
| Key Words:  |           |                            | Steven A. Rathofer, D.D.S., |                          |           |
| Inflammatory papillary hyperplasia  |           |                            | LTC, DC                     |                          |           |
| Electrosurgery  |           |                            |                             |                          |           |
| Surgical blade loops  |           |                            |                             |                          |           |
| Accumulative MEDCASE Cost:  |           | Est Accumulative OMA Cost: |                             | Periodic Review Results: |           |
| Objective: To compare clinical healing time and subjective relative patient discomfort between the two methods of inflammatory papillary hyperplasia removal. |           |                            |                             |                          |           |

Technical Approach: Split mouth comparison. Subjective responses measured by questionnaire.

Progress: Twenty patients were entered on the study. Initial evaluation shows no difference in acceptance of techniques in the total patient population.

# Detail Summary Sheet

Date: 17 Nov 83 Proj No: SWOG 7713/14 Status: Closed

## TITLE:

Chemoimmunotherapy in Non-Hodgkin's Lymphoma.

|                            |  |                          |                              |
|----------------------------|--|--------------------------|------------------------------|
| Start Date                 | FY 78  | Est Comp Date:           | Unknown                      |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC             | Facility                 | Brooke Army Medical Center   |
| Dept/Sec                   | Department of Medicine/Oncology              | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | Chemoimmunotherapy<br>Non-Hodgkin's Lymphoma |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:                   | Periodic Review Results: |                              |

Objectives: To compare the effectiveness, in terms of rate of response of two chemoimmunotherapy regimens (CHOP + Levamisole vs CHOP + Levamisole + BCG) against CHOP for remission induction in previously untreated patients with non-Hodgkin's lymphoma.

For patients proven to be in complete remission after induction, to compare the duration of documented complete response obtained by continued maintenance immunotherapy with Levamisole vs no maintenance therapy.

For patients with impaired cardiac function (not eligible for treatment with Adriamycin), with mycosis fungoides, or with only a partial response to 11 courses of treatment with CHOP-Levamisole + BCG, to estimate the complete response rate obtained by continued chemoimmunotherapy with COP + Levamisole.

To estimate the CNS relapse rate in patients with diffuse lymphomas when CNS prophylaxis with intrathecal cytosine arabinoside is used.

To continue to evaluate the impact of systemic restaging of patients judged to be in complete remission and the value of expert hematopathology review of diagnostic material from all cases.

To establish baseline and serial data on immunologic status in both chemo-immunotherapy groups.

Technical Approach: The patient must have the diagnosis of non-Hodgkin's lymphoma established by biopsy.

Therapy will follow the schema outlined in the study protocol.

Progress: Study closed because of poor patient accrual.

# Detail Summary Sheet

|  |                              |                |
|--|------------------------------|----------------|
| Date: 17 Nov 83  | Proj No: SWOG 7727           | Status: Closed |
| TITLE: Combination Chemoimmunotherapy Utilizing BCNU, Hydroxyurea and DTIC with Levamisole vs DTIC plus Actinomycin-D in the Treatment of Patients with Disseminated Malignant Melanoma. |                              |                |
| Start Date: FY 78  | Est Comp Date:               |                |
| Principal Investigator   | Facility                     |                |
| J. Dean McCracken, M.D., COL, MC   | Brooke Army Medical Center   |                |
| Dept/Sec   | Associate Investigators:     |                |
| Department of Medicine/Oncology  | James F. Boyd, M.D., LTC, MC |                |
| Key Words:   |                              |                |
| Chemoimmunotherapy   |                              |                |
| Malignant melanoma   |                              |                |

|  |                  |                 |
|--|------------------|-----------------|
| Accumulative MEDCASE   | Est Accumulative | Periodic        |
| Cost:  | OMA Cost:        | Review Results: |
| Objective: To determine remission induction rates, remission duration, survival and toxicity in patients with disseminated malignant melanoma treated with BCNU, Hydroxyurea, and DTIC (BHD), BHD plus Levamisole, and intermittent single high dose DTIC plus Actinomycin-D in a prospective randomized clinical study. |                  |                 |

Technical Approach: Patients with histologically proven disseminated malignant melanoma who have not been treated previously with any of the protocol agents shall be eligible. Patients must have measurable disease and estimated survival of at least two months.

Therapy will follow the schema outlined in the study protocol.

Progress: There has been no change in response data, toxicity, prognostic factors or survival. Median survival for DTIC + Actinomycin-D patients is 33 weeks; 27 weeks for BHD patients and 19 weeks for Levamisole patients.

The study has been closed to new patient entries. No patients from BAMC were entered on this study during FY 83.

# Detail Summary Sheet

|  |           |                            |                              |                          |         |
|--|-----------|----------------------------|------------------------------|--------------------------|---------|
| Date:  | 17 Nov 83 | Proj No:                   | SWOG 7804                    | Status:                  | Ongoing |
| TITLE: Adjuvant Chemotherapy with 5-Fluorouracil, Adriamycin and Mitomycin-C (FAM) vs Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma. |           |                            |                              |                          |         |
| Start Date   |           |                            | FY 78                        |                          |         |
| Principal Investigator   |           |                            | Est Comp Date:               |                          |         |
| J. Dean McCracken, M.D., COL, MC   |           |                            | Facility                     |                          |         |
| Dept/Sec   |           |                            | Brooke Army Medical Center   |                          |         |
| Department of Medicine/Oncology  |           |                            | Associate Investigators:     |                          |         |
| Key Words:   |           |                            | James F. Boyd, M.D., LTC, MC |                          |         |
| Gastric adenocarcinoma   |           |                            |                              |                          |         |
| Chemotherapy   |           |                            |                              |                          |         |
| Disease-free interval  |           |                            |                              |                          |         |
| Accumulative MEDCASE Cost:   |           | Est Accumulative OMA Cost: |                              | Periodic Review Results: |         |
|  |           |                            |                              | Continue                 |         |

Objective: To determine the efficacy of adjuvant chemotherapy with 5-FU, Adriamycin and Mitomycin-C (FAM) on the disease-free interval and survival of patients with TNM stage-group IB, IC, II and III gastric adenocarcinoma compared to potentially curative surgery alone.

Technical Approach: Eligible patients must have localized lesions at least extending into the submucosa and involving any of the deeper layers with the maximum allowable penetration into but not through the serosa; localized lesions extending through serosa, with or without direct extension to contiguous structures; a lesion diffusely involving the wall of the stomach with or without metastases to immediately adjacent perigastric nodes or a localized lesion of any depth with metastases to perigastric nodes in the immediate vicinity; a localized or diffuse lesion with metastases to perigastric nodes distant from primary.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, 100 patients have been registered on this study (two from BAMC). No difference has been seen in survival rate or disease free interval. The median survival after relapse has been three months for the control arm and one month for FAM.

# Detail Summary Sheet

|   |                            |                                   |           |         |         |
|---|----------------------------|-----------------------------------|-----------|---------|---------|
| Date:   | 17 Nov 83                  | Proj No:                          | SWOG 7808 | Status: | Ongoing |
| TITLE:  |                            |                                   |           |         |         |
| Combination Modality Treatment for Stage III and IV Hodgkin's Disease MOPP 6. |                            |                                   |           |         |         |
| Start Date  | FY 79                      | Est Comp Date:                    |           |         |         |
| Principal Investigator  |                            | Facility                          |           |         |         |
| J. Dean McCracken, M.D., COL, MC  |                            | Brooke Army Medical Center        |           |         |         |
| Dept/Sec  |                            | Associate Investigators:          |           |         |         |
| Department of Medicine/Oncology   |                            | James F. Boyd, M.D., LTC, MC      |           |         |         |
| Key Words:  |                            |                                   |           |         |         |
| Hodgkin's disease   |                            |                                   |           |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: Continue |           |         |         |

Objectives: To attempt to increase the complete remission rate induced with MOP-BAP alone utilizing involved field radiotherapy in patients with Stages III and IV Hodgkin's disease achieving a partial response at the end of six cycles of MOP-BAP.

To determine if immunotherapy maintenance with levamisole or consolidation with low dose involved field radiotherapy will produce significantly longer remission durations over a no further treatment group when complete response has been induced with six cycles of MOP-BAP in Stages III and IV Hodgkin's disease.

Technical Approach: Eligible patients must have a histological diagnosis of Hodgkin's which must be classified by the Lukes and Butler system.

Therapy will follow the schema outlined in the study protocol.

Progress: The preliminary complete remission rate is 55%. Information on administration of radiation therapy to patients achieving a partial response indicates a high likelihood of converting partial responses to complete responses. No new patients from BAMC were entered on this study during FY 83.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7823/4/5/6 Status: Ongoing

## TITLE:

ROAP-AdOAP in Acute Leukemia

|                            |   |                          |                              |
|----------------------------|---|--------------------------|------------------------------|
| Start Date                 | FY 79   | Est Comp Date:           | Unknown                      |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC                      | Facility                 | Brooke Army medical Center   |
| Dept/Sec                   | Department of Medicine/Oncology                       | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | Chemotherapy<br>Immunotherapy<br>Adult acute leukemia |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:                            | Periodic Review Results: | Continue                     |

Objectives: To compare the efficacy of the 4-drug combination chemotherapy regimen, ROAP (Rubidazone, vincristine, arabinosyl cytosine, and prednisone) to AdOAP (the same combination using Adriamycin in place of Rubidazone) in adult acute leukemia, as determined by remission rate, remission duration and survival.

To determine the comparative toxicity of these regimens.

To determine whether late intensification therapy at 9 months after complete remission will improve long-term, disease-free survival.

To determine whether immunotherapy using levamisole for 6 months after 12 months of complete remission on chemotherapy improves disease-free survival.

To determine the effects of intrathecal Ara-C on the incidence of CNS leukemia.

To determine reproducibility of the FAB/histologic classification and correlation to response to therapy in 200 consecutive cases of acute leukemia.

To study the effects of intensive supportive care in the management of acute leukemia.

Technical Approach: All patients over 15 with a diagnosis of acute leukemia who have not received extensive therapy (defined as more than one course of any other chemotherapeutic agent or combination of agents) will be eligible for this study. The diagnosis of acute leukemia will be made on bone marrow smear, clot section and/or biopsy. An absolute infiltrate of 50% leukemic cells or greater is required.

Progress: Groupwide patient accrual has been excellent (13 from BAMC). The complete response rate remains approximately 60%.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7827 Status: Ongoing

## TITLE:

Combined Modality Therapy for Breast Carcinoma, Phase III

|                            |                                  |                                   |
|----------------------------|----------------------------------|-----------------------------------|
| Start Date                 | FY 80                            | Est Comp Date: Unknown            |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC | Facility                          |
| Dept/Sec                   | Department of Medicine/Oncology  | Brooke Army Medical Center        |
| Key Words:                 | Receptor positive (ER+)          | Associate Investigators:          |
|                            | Chemotherapy                     | James F. Boyd, M.D., LTC, MC      |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:       | Periodic Review Results: Continue |

Objectives: To compare the disease-free interval and recurrence rates in estrogen receptor positive (ER+) premenopausal patients with Stage II disease, using combination chemotherapy alone versus chemotherapy and oophorectomy.

To compare the disease-free interval and recurrence rates in estrogen receptor positive postmenopausal patients with Stage II disease, using combination chemotherapy plus tamoxifen versus tamoxifen alone versus combination chemotherapy alone.

To compare the disease-free interval and recurrence rates in all estrogen receptor negative (ER-) patients with Stage II disease using one versus two years of combination chemotherapy.

To compare the effect of these various adjunctive therapy programs upon the survival patterns of such patients.

To correlate the ER status with disease-free interval and survival.

Technical Approach: All patients must have had a radical or modified radical mastectomy with histologically proven breast cancer and with one or more pathologically proven axillary nodes. Primary neoplasm and clinically apparent axillary disease must be completely removed. Pretherapy studies must reveal no evidence of metastatic disease or involvement of the other breast. Patients with postoperative radiation therapy are eligible but will be randomized and evaluated separately. Therapy will follow the schema outlined in the protocol.

Progress: Thirty-two patients from BAMC have been entered on this study, three during FY 83. No conclusions have been drawn with regard to the various treatment arms.



# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7841 Status: Ongoing

## TITLE:

Phase II-III Comparison of FAM vs FAM + Vincristine vs Chlorozbtocin in the Treatment of Advanced Gastric Adenocarcinoma.

Start Date FY 79 Est Comp Date: Unknown

Principal Investigator J. Dean McCracken, M.D., COL, MC Facility Brooke Army Medical Center

Dept/Sec Department of Medicine/Oncology Associate Investigators: James F. Boyd, M.D., LTC, MC

Key Words: Chemotherapy Gastric adenocarcinoma Chlorozotocin

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine whether or not vincristine increases the effectiveness (as determined by response rate and survival) of 5-FU plus mitomycin-C plus Adriamycin (FAM) in the treatment of advanced, previously untreated gastric adenocarcinoma.

To determine the efficacy, as determined by response rate and survival of chlorozotocin in the treatment of previously untreated gastric adenocarcinoma.

To determine by crossover, after relapse or failure on FAM, V-FAM or chlorozotocin, the effectiveness as determined by response rate and survival, of the alternate treatment in advanced gastric adenocarcinoma with prior therapy.

To determine the toxicities of such treatments.

Technical Approach: Patients must have histologically proven adenocarinoma, Stage IV in extent, to be eligible for this study. They must not have received prior chemotherapy nor should they have received radiotherapy within four weeks of entry. Patients must have a minimum life expectancy of 6 weeks and a performance status of 0-3 in order to be eligible.

The protocol has been amended and arms being used are FAM vs DHAD.

Progress: Patient accrual has been slow. The study remains open until 25 patients have been entered on the DHAD arm. No patients from BAMC have been enrolled on this study.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7902 Status: Completed  
 TITLE:  
 Combined Modality Therapy for Head and Neck Cancer.

|                            |   |                          |                              |
|----------------------------|---|--------------------------|------------------------------|
| Start Date                 | FY 80   | Est Comp Date:           | Unknown                      |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC                          | Facility                 | Brooke Army Medical Center   |
| Dept/Sec                   | Department of Medicine/Oncology                           | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | Head and neck cancer<br>Chemotherapy<br>Radiation therapy |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:                                | Periodic Review Results: |                              |

Objectives: To compare the survival of Stage III and IV squamous cell carcinoma of the tongue, oral cavity, tonsil, oropharynx, hypopharynx and larynx subjected to radiation therapy followed by surgical excision, if possible, vs survival of patients subjected to chemotherapy with Cis-platinum, Oncovin and Bleomycin (COB), followed by radiation therapy and surgical excision if possible.

To determine the incidence and extent of complications arising from chemotherapy and radiotherapy followed by head and neck surgery vs radiotherapy and head and neck surgery.

Technical Approach: Previously untreated patients with a histologically confirmed diagnosis of advanced inoperable squamous cell carcinoma of the head and neck, Stages III and IV, of the oral cavity, tongue, tonsil, oropharynx, hypopharynx and larynx are eligible. There must be an evaluable lesion(s). Patients must have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC were entered on this study. The study was closed due to poor patient accrual.

Detail Summary Sheet

|  |  |                                   |
|--|--|-----------------------------------|
| Date: 28 Oct 83  | Proj No: SWOG 7916                                       | Status: Ongoing                   |
| TITLE:<br>Phase II Evaluation of Gallium Nitrate in Metastatic Urological Malignancies: Testicular, Bladder, Prostate and Kidney |  |                                   |
| Start Date FY 80   | Est Comp Date: Unknown                                   |                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC   | Facility<br>Brooke Army Medical Center                   |                                   |
| Dept/Sec<br>Department of Medicine/Oncology  | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |                                   |
| Key Words:<br>Metastatic urological malignancies<br>Gallium nitrate  |  |                                   |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:                               | Periodic Review Results: Continue |

Objective: To determine the efficacy of Gallium Nitrate, as determined by response rate, duration of response and survival, in patients with metastatic urological malignancies which include: testicular, bladder, prostate and kidney; who have failed on higher priority treatment protocols.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic urological malignancies are eligible. Patients should not have had more than two previous types of combination or single agent chemotherapy trials. Patients must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study remains open to bladder cancer patients only. Gallium nitrate appears to be an active drug in bladder cancer.

No patients from BAMC have been entered on this study.

# Detail Summary Sheet

|   |                            |  |                   |
|---|----------------------------|--|-------------------|
| Date: 18 Nov 83   |                            | Proj No: SWOG 7922                                       | Status: Completed |
| TITLE: Combination of CTX, Adria and Cis-Platinum vs m-AMSA in Patients with Advanced Transitional Cell Cancer of the Urinary Bladder with Good Renal Function, Phase II-III. |                            |  |                   |
| Start Date FY 81  |                            | Est Comp Date: Unknown                                   |                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC  |                            | Facility<br>Brooke Army Medical Center                   |                   |
| Dept/Sec<br>Department of Medicine/Oncology   |                            | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |                   |
| Key Words:<br>Transitional cell bladder cancer  |                            |  |                   |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results:                                 |                   |

Objectives: To determine the response rate to the combination chemotherapy of CAP vs m-AMSA in patients with advanced transitional cell carcinoma of the urinary bladder not amenable by surgical resection and/or radiotherapy, who have good renal function.

To determine the response rate to CAP vs m-AMSA after failure or progression on either arm upon crossover to the alternate treatment arm.

Technical Approach: Patients with histologic diagnosis of transitional cell carcinoma of the urinary bladder, Stage IV, or patients who have failed on previous surgery and/or radiotherapy are eligible. Patients must have measurable disease and a life expectancy of at least 8 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: It appears that survival has not been prolonged with chemotherapy.

No patients from BAMC were entered on this study during FY 83.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7924 Status: Completed  
TITLE:

Multimodal Therapy for Limited Small Cell Carcinoma of the Lung, Phase III.

|  |  |
|--|--|
| Start Date FY 80   | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Small cell carcinoma of lung                 |  |

|                               |                               |                             |
|-------------------------------|-------------------------------|-----------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: |
|-------------------------------|-------------------------------|-----------------------------|

Objectives: To determine the efficacy of sequentially alternating mutually noncross-resistant, multidrug regimens in remission induction and intensification therapy in patients with limited small cell lung cancer.

To determine the value of chest radiotherapy added to intensive systemic chemotherapy in reducing chest recurrences and in improvement of survival.

To determine the relative efficacy and toxicity of low-dose, extensive chest radiation when used in close chronologic sequence with systemic multi-agent chemotherapeutic regimens.

To determine whether radiotherapy ports should be set according to tumor size prior to or after induction chemotherapy.

To determine the value of combined systemic chemotherapy and radiotherapy in the control of bulky chest disease.

Technical Approach: Patients with histologically or cytologically proven small cell carcinoma of the lung will be eligible for this study. All patients must have so-called "limited disease".

Therapy will follow the schema outlined in the study protocol.

Progress: It appeared that radiation therapy benefited the disease free interval in CR patients over that of no radiation therapy.

No patients from BAMC were entered on this study during FY 83.

# Detail Summary Sheet

|  |                            |  |                 |
|--|----------------------------|--|-----------------|
| Date: 18 Nov 83  |                            | Proj No: SWOG 7925                                       | Status: Ongoing |
| TITLE:<br>Chemoimmunotherapy in Stages III and IV Ovarian Carcinoma: A-C plus BCG, vs A-C plus Cis-Platinum, vs A-C plus Cis-Platinum plus BCG, Phase III. |                            |  |                 |
| Start Date FY 80   |                            | Est Comp Date: Unknown                                   |                 |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC   |                            | Facility<br>Brooke Army Medical Center                   |                 |
| Dept/Sec<br>Department of Medicine/Oncology  |                            | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |                 |
| Key Words:<br>Ovarian carcinoma<br>Chemoimmunotherapy  |                            |  |                 |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: Continue                        |                 |

Objectives: To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum for remission and induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the effectiveness of A-C + Cis-Platinum vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival in patients with Stage III and IV ovarian carcinoma.

To compare the effectiveness of A-C + BCG vs A-C + Cis-Platinum + BCG for remission induction and/or maintenance of disease-free status and prolongation of survival duration in patients with Stages III and IV ovarian carcinoma.

To compare the toxicities of the A-C + BCG, A-C + Cis-Platinum and A-C + Cis-Platinum + BCG regimens.

Technical Approach: Only patients with epithelial type neoplasms will be eligible for this study. The patient must have histologically confirmed diagnosis of ovarian carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: Fewer patients have been entered on the A-C + Cis-Platinum treatment arm. Thus, it is difficult to draw conclusions concerning the preliminary data with respect to differences in response rates between the three treatment arms. Nevertheless, there is at this point, a statistical difference ( $P=.012$ ) in complete plus partial response rates between the three groups with the A-C + BCG treated patients having the lowest CR + PR rate (36%). When patients with an "improved status" are included, there are no statistical differences between the three treatment arms.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7927/8 Status: Closed

## TITLE:

Chemotherapy for Multiple Myeloma, Phase III.

|                            |                                  |                          |                              |
|----------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date                 | FY 80                            | Est Comp Date:           | Unknown                      |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec                   | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | Multiple myeloma<br>Chemotherapy |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:       | Periodic Review Results: |                              |

Objectives: To compare the effectiveness of four different drug combinations for remission induction in previously untreated patients with multiple myeloma.

For patients with a 75% tumor reduction, to evaluate the role of 12 months of chemotherapy maintenance with VCP or VCP plus levamisole, when compared with previous experiences.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma will be eligible for this study. Patients should have objective evidence of and be symptomatic from complications due to myeloma.

Therapy will follow the schema outlined in the study protocol.

Progress: The VMCP-VBAP + Levamisole arm has had the highest response rate, but both Levamisole induction arms have had a slightly higher frequency of early deaths although not a significant number.

The study has been closed to new entries. One patient from BAMC was entered on this study during FY 83.

# Detail Summary Sheet

|   |                            |                   |
|---|----------------------------|-------------------|
| Date: 18 Nov 83   | Proj No: SWOG 7936         | Status: Completed |
| TITLE: Evaluation of Mitomycin-C + Vincristine + Bleomycin + Cis-Platinum vs Mitomycin-C + Cis-Platinum vs Cis-Platinum in the Treatment of Disseminated Carcinoma of the Uterine Cervix, Phase II. |                            |                   |
| Start Date FY 80  | Est Comp Date: Unknown     |                   |
| Principal Investigator  | Facility                   |                   |
| J. Dean McCracken, M.D., COL, MC  | Brooke Army Medical Center |                   |
| Dept/Sec  | Associate Investigators:   |                   |
| Department of Medicine/Oncology   | James F. Boyd, LTC, MC     |                   |
| Key Words:  |                            |                   |
| Uterine cervix carcinoma  |                            |                   |

|   |                            |                          |
|---|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To determine the response rate, duration of responses, and survival of (1) cis-platinum alone, (2) cis-platinum combined with mitomycin-C, and (3) cis-platinum with mitomycin-C, vincristine, and bleomycin, in patients with advanced squamous cell carcinoma of the cervix no longer amenable to surgery or radiation therapy. |                            |                          |

To document the nature and extent of the hematologic and non-hematologic side effects of the above three drug regimens.

Technical Approach: All patients with incurable squamous cell carcinoma of the uterine cervix who are not candidates for surgery or radiotherapy and are not eligible for higher priority SWOG studies are eligible. Patients must have no uncontrolled active or potentially active site of infection, must have at least one measurable lesion and must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The study has been closed because of poor patient accrual. No patients from BAMC were entered on this study.



# Detail Summary Sheet

Date: 18 Nov 82 Proj No: SWOG 7937 Status: Completed

## TITLE:

Evaluation of m-AMSA in Metastatic Carcinoma of the Genitourinary Tract Except Renal Carcinoma, Phase II.

|                        |  |  |
|------------------------|--|--|
| Start Date             | FY 80  | Est Comp Date: Unknown                                   |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC                   | Facility   |
| Dept/Sec               | Department of Medicine/Oncology                    | Brooke Army Medical Center                               |
| Key Words:             | Metastatic genitourinary tract carcinoma<br>m-AMSA | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the antitumor activity of AMSA, as determined by response rate, duration of response, and survival, in patients with metastatic carcinoma of the genitourinary tract who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of this drug.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven, incurable, advanced, metastatic carcinoma will be eligible. Patients must have clearly measurable disease and a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: m-AMSA appears to have no activity in cancer of the genitourinary tract. No patients from BAMC were entered on this study during FY 83.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7956 Status: Ongoing

## TITLE:

Study of Postinfarction Nephrectomy and Medroxyprogesterone Acetate (Depo-Provera) in Metastatic Renal Cell Carcinoma.

|                            |   |                          |                              |
|----------------------------|---|--------------------------|------------------------------|
| Start Date                 | FY 80   | Est Comp Date:           | Unknown                      |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC  | Facility                 | Brooke Army Medical Center   |
| Depo/Sec                   | Department of Medicine/Oncology   | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | Metastatic renal cell carcinoma<br>Postinfarction nephrectomy<br>Depo-Provera |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:  | Periodic Review Results: | Continue                     |

Objectives: To determine the response rate and survival patterns in patients with disseminated renal cell carcinoma treated with postinfarction nephrectomy.

To determine the response rate and survival patterns of patients with disseminated renal cell carcinoma who relapse or do not respond to postinfarction nephrectomy when treated with Depo-Provera.

Technical Approach: Patients with measurable disseminated renal cell carcinoma who have not had removal of the primary cancer and in whom the metastatic disease is not resectable at the time of nephrectomy are eligible. Patients must have an expected survival of at least 3 months.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was amended to administer the Depo-Provera immediately following infarction prior to a nephrectomy. One patient from BAMC has been entered on the study; however, no reportable data are available at this time.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7958 Status: Closed

## TITLE:

Evaluation of m-AMSA in Metastatic or Recurrent Epithelial Carcinomas of the Female Genital Tract.

|                        |  |                          |                              |
|------------------------|--|--------------------------|------------------------------|
| Start Date             | FY 80  | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC                       | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology                        | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Epithelial carcinoma of female genital tract<br>m-AMSA |                          |                              |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the antitumor activity of AMSA in patients with metastatic or recurrent epithelial carcinomas of the ovary, endometrium, cervix, vagina or vulva who have failed on higher priority treatment protocols.

To determine the nature and degree of toxicity of AMSA in patients treated by the split-course three-day schedule.

Technical Approach: All patients not eligible for higher priority SWOG studies with histologically proven incurable, advanced, metastatic or recurrent epithelial carcinoma of the ovary, endometrium, cervix, vagina or vulva are eligible. Patients must have clearly measurable disease and a life expectancy of 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed due to ineffectiveness of m-AMSA and poor patient accrual. No patients from BAMC were entered on the study.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7983 Status: Ongoing

## TITLE:

Radiation Therapy in Combination with CCNU in Patients with Incompletely Resected Gliomas of the Brain, Grade I and II.

|                        |                                     |                          |                            |
|------------------------|-------------------------------------|--------------------------|----------------------------|
| Start Date             | FY 80                               | Est Comp Date:           | Unknown                    |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC    | Facility                 | Brooke Army Medical Center |
| Dept/Sec               | Department of Medicine/Oncology     | Associate Investigators: | James F. Boyd, LTC, MC     |
| Key Words:             | Glioma<br>Radiation therapy<br>CCNU |                          |                            |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To compare the survival of patients with incompletely resected Grade I and II gliomas treated with radiation alone versus radiation and CCNU.

To compare the effectiveness of radiation therapy versus radiation therapy plus CCNU for remission induction and duration of remission.

Technical Approach: Patients with histologically confirmed primary brain tumors of the following histologic types are eligible: Astrocytoma, Grade I and II with incomplete tumor resection. Patients who have had surgery with histologic diagnosis within the previous six weeks are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study during FY 83. No reportable data are available at this time.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7984 Status: Ongoing

## TITLE:

Treatment of Chronic Stage CML with Pulse, Intermittent Busulfan Therapy with or without Oral Vitamin-A, Phase III

|                        |                                   |                          |                              |
|------------------------|-----------------------------------|--------------------------|------------------------------|
| Start Date             | Nov 80                            | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC  | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology   | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Leukemia<br>Busulfan<br>Vitamin A |                          |                              |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objective: To determine the efficacy of standard pulse, intermittent busulfan therapy plus oral vitamin A in prolonging the chronic phase of CML, and hence in prolonging survival.

Technical Approach: All patients with newly diagnosed chronic stage CML will be eligible for entry onto protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: Patients accrual continues to be slow. One patient from BAMC has been entered on the study.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 7990 Status: Ongoing

## TITLE:

Testicular Cancer Intergroup Study.

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | FY 80                            | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Testicular cancer                |                          |                              |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To compare the disease-free survival and overall survival for surgery alone (with chemotherapy for relapsers) vs surgery plus early adjuvant chemotherapy in patients with resectable Stage II testicular cancer.

To register and follow patients with non-seminoma, non-choriocarcinoma stage I testicular cancer, to define prognostic variables which may predict recurrence in this stage group.

To define the difference in disease-free rates and patterns of recurrence based upon histologic subtypes and extent of disease on initial presentation.

To evaluate the role of marker substances such as human chorionic gonadotropin, alpha-fetoprotein and lactic dehydrogenase in the early detection and management of recurrences in patients with stage I and stage II testicular carcinoma.

To evaluate the accuracy of lymphangiogram, CAT scans and ultrasound studies for staging of retroperitoneal nodal involvement.

Technical Approach: Patients with histologically confirmed carcinoma of the testis, stage I or stage II, are eligible. Patients should enter the study between two and four weeks after lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available. Thus far, only one patient from BAMC has been entered into this study.

# Detail Summary Sheet

Date: 18 Nov 83      Proj No: SWOG 8001      Status: Ongoing  
 TITLE:

Evaluation of Two Maintenance Regimens in the Treatment of Acute Lymphoblastic Leukemia in Adults, Phase III.

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | FY 80                            | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Acute lymphoblastic leukemia     |                          |                              |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objective: To evaluate the effectiveness as determined by the complete remission rate of the L10 protocol using Vincristine, Prednisone and Adriamycin for induction, followed by intensive consolidation in the treatment of acute ALL.

To compare the effect on remission duration and survival of two maintenance regimens: the L10 "eradication" regimen vs cyclic therapy with POMP-COAP-OPAL.

To determine the reproducibility of the FAB histologic classification and correlation to response to therapy of ALL in adults.

Technical Approach: Patients are eligible with the diagnosis of acute lymphoblastic leukemia who satisfy the following criteria: A) Absolute infiltration of the marrow with >50% blasts; b) Absolute infiltration is defined as the total blast cell percentage (%) multiplied by the bone marrow cellularity percentage divided by 100; B) If the absolute infiltrate is 30-49%, evidence of progressive disease prior to entering the study will be required.

Therapy will follow the schema outlined in the study protocol.

Progress: Response continues to be excellent. No new patients from BAMC have been entered on this study.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8005 Status: Closed

## TITLE:

Evaluation of DHAD in Refractory Malignant Lymphomas, Phase II - Pilot.

|                            |                                  |                          |                              |
|----------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date                 | 11 May 81                        | Est Comp Date:           |                              |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec                   | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | DHAD<br>Malignant lymphoma       |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:       | Periodic Review Results: |                              |

Objectives: To determine response rate and response duration of patients with refractory malignant lymphomas, both Hodgkin's disease and non-Hodgkin's lymphoma treated with anthracenedione used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of anthracenedione in a Phase II study.

Technical Approach: All patients with malignant lymphoma who are not eligible for higher priority SWOG protocols are eligible. There are no age restrictions and patients must have a life expectancy of at least 6 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: The study was closed due to poor responses. No patients from BAMC were entered on the study.



# Detail Summary Sheet

|  |                                  |                          |                          |                              |         |
|--|----------------------------------|--------------------------|--------------------------|------------------------------|---------|
| Date:  | 18 Nov 83                        | Proj No:                 | SWOG 8006                | Status:                      | Ongoing |
| TITLE: Postoperative Reductive Chemotherapy for Stage III or IV Operable Epidermoid Carcinoma of the Oral Cavity, Oropharynx, Hypopharynx, or Larynx, Phase III. |                                  |                          |                          |                              |         |
| Start Date   | Nov 80                           | Est Comp Date:           | Unknown                  |                              |         |
| Principal Investigator   | J. Dean McCracken, M.D., COL, MC |                          | Facility                 | Brooke Army Medical Center   |         |
| Dept/Sec   | Department of Medicine/Oncology  |                          | Associate Investigators: | James F. Boyd, M.D., LTC, MC |         |
| Key Words:   | Epidermoid carcinoma             |                          |                          |                              |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:       | Periodic Review Results: | Continue                 |                              |         |

Objective: To determine the length of remission, recurrence rates, survival rates, and pattern of recurrence for patients receiving therapy utilizing surgery and postoperative radiation vs combined therapy utilizing preoperative chemotherapy, surgery and postoperative radiation therapy in operable Stage III or IV epidermoid carcinoma of the head and neck.

Technical Approach: Patients with operable lesions will be randomized between two therapeutic programs: Arm 1 - combined therapy including surgery and postoperative radiation therapy; or Arm 2 - combination chemotherapy followed by surgery and radiation therapy. Patients randomized to the chemotherapy limb will receive three courses of chemotherapy consisting of cis-platinum, methotrexate, vincristine and bleomycin.

Therapy will follow the schema outlined in the study protocol.

Progress: A total of twenty patients from BAMC have been entered on this study. Ten remain on the study and the remaining ten have either expired or placed on other therapy. Groupwise, no reportable data are available.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8008 Status: Closed

## TITLE:

Evaluation of Dihydroxyanthracenedione (DHAD) in Refractory Breast Cancer, Phase II.

|                        |                                  |                              |
|------------------------|----------------------------------|------------------------------|
| Start Date             | FY 80                            | Est Comp Date:               |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                     |
| Dept/Sec               | Department of Medicine/Oncology  | Brooke Army Medical Center   |
| Key Words:             | Breast cancer                    | Associate Investigators:     |
|                        | Dehydroxyanthracenedione (DHAD)  | James F. Boyd, M.D., LTC, MC |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the response rate and remission duration of refractory breast cancer in patients treated with anthracenedione used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of breast cancer. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: DHAD has limited activity in heavily treated patients with advanced breast cancer. Therefore, the study is closed. No patients from BAMC were entered on the study during FY 83.

# Detail Summary Sheet

Date: 18 Nov 83      Proj No: SWOG 8009      Status: Closed  
 TITLE:

Evaluation of DHAD in Patients with Refractory Small Cell Lung Cancer, Phase II.

|  |  |
|--|--|
| Start Date      FY 80                                      | Est Comp Date:   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Small cell lung cancer<br>DHAD               |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the response rate and remission duration of refractory small cell lung cancer in patients treated with DHAD used in a single dose every three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: Eligible patients must have pathologically verified histologic diagnosis of small cell lung cancer. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed because of poor patient accrual.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8012 Status: Completed

## TITLE:

Treatment for Advanced Adenocarcinoma and Large Cell Carcinoma of the Lung: FOMi vs CAP vs FOMi/CAP, Phase III.

|  |  |
|--|--|
| Start Date - Jan 81  | Est Comp Date:   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC   | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                  | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Adenocarcinoma<br>Large cell carcinoma<br>Lung |  |
| Accumulative MEDCASE<br>Cost:                                | Est Accumulative<br>OMA Cost:                            |
|  | Periodic<br>Review Results:                              |

Objectives: To evaluate by pairwise comparison the response rate, duration of response, and survival of 3 regimens FOMi, CAP, and FOMi/CAP in patients with advanced (TMN Stage III M<sub>1</sub>) adenocarcinoma and large cell undifferentiated carcinoma of the lung.

To evaluate the degree of non-cross resistance of FOMi in CAP failures and of CAP on FOMi failures.

To compare the toxicities and side effects of FOMi and CAP.

Technical Approach: Patients are eligible who have a histologically confirmed diagnosis of adenocarcinoma of the lung or large cell undifferentiated carcinoma of the lung. All patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: A total of 21 patients from BAMC have been entered into this study (one during FY 83). Ten remain on the study. Groupwise, there has been a median survival advantage (28 weeks) with the FOMi/CAP arm which is significantly superior to the other two arms. This may represent the first regimen shown in a cooperative group to prolong survival benefit in patients with this regimen as the best arm for comparison in future protocols.

This study has been closed to new entries.

# Detail Summary Sheet

|   |  |                             |
|---|--|-----------------------------|
| Date: 18 Nov 83   | Proj No: SWOG 8015                                       | Status: Completed           |
| TITLE: Evaluation of Two Combination Chemotherapy Programs, Adriamycin and Cis-Platinum (AP) vs Adriamycin, Cis-platinum plus VP-16 (VAP), in the Treatment of Extensive Squamous Cell Carcinoma of the Lung, Phase III |  |                             |
| Start Date Jan 81   | Est Comp Date:   |                             |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC  | Facility<br>Brooke Army Medical Center                   |                             |
| Dept/Sec<br>Department of Medicine/Oncology   | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |                             |
| Key Words:<br>Lung<br>Squamous cell carcinoma   |  |                             |
| Accumulative MEDCASE<br>Cost:   | Est Accumulative<br>OMA Cost:                            | Periodic<br>Review Results: |

Objectives: To determine the activity, in terms of response-rate, remission duration, and survival in patients with extensive squamous cell (epidermoid) carcinoma of the lung, for two combination chemotherapy programs: Adriamycin and Cis-platinum vs VP-16, Adriamycin and Cis-platinum.

To evaluate the relative toxicities of these respective regimens.

To assess the feasibility and reliance of applying "measurable versus evaluable" criteria of tumor regression in determining therapeutical response.

To correlate tumor grade with response and survival.

Technical Approach: Eligible patients are those with "extensive" squamous cell (epidermoid) lung carcinoma defined as "spread beyond the hemithorax and ipsilateral scalene, supraclavicular and mediastinal lymph nodes", equivalent with TNM system Stage III class M<sub>1</sub> with any T or N other than mediastinal, supraclavicular scalene nodes involved. Relapsing or recurrent TNM Stage I or II patients, failing after radiation therapy alone to the primary site of involvement are also eligible for study.

Therapy will follow the schema outlined in the study protocol.

Progress: Groupwide, the response rates have been low. There appears to be no apparent advantage with the addition of VP-16 to the AP combination.

No patients from BAMC were entered on this study during FY 83.

# Detail Summary Sheet

|   |           |                        |                              |         |         |
|---|-----------|------------------------|------------------------------|---------|---------|
| Date:   | 18 Nov 83 | Proj No:               | SWOG 8017                    | Status: | Ongoing |
| TITLE:  |           |                        |                              |         |         |
| 5-FU, Adriamycin, Streptozotocin and Cyclophosphamide (FAC-S) in the Treatment of Metastatic Carcinoid Tumors, Phase II |           |                        |                              |         |         |
| Start Date  | Nov 80    | Est Comp Date: Unknown |                              |         |         |
| Principal Investigator  |           |                        | Facility                     |         |         |
| J. Dean McCracken, M.D., COL, MC  |           |                        | Brooke Army Medical Center   |         |         |
| Dept/Sec  |           |                        | Associate Investigators:     |         |         |
| Department of Medicine/Oncology   |           |                        | James F. Boyd, M.D., LTC, MC |         |         |
| Key Words:  |           |                        |                              |         |         |
| Carcinoid   |           |                        |                              |         |         |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine whether combination chemotherapy employing 5-FU, Cyclophosphamide, Adriamycin and Streptozotocin is effective in the management of metastatic carcinoid.

To study the duration of survival of patients with metastatic carcinoid tumor treated with combination chemotherapy regimens.

To provide further information concerning the response and/or survival of patients with metastatic carcinoid originating in different sites and having different metastatic patterns.

Technical Approach: All patients must have biopsy-proven carcinoid tumor not amenable to further surgical therapy with no prior chemotherapy. A minimum life expectancy of 6 weeks and a performance status of 3 or better per Southwest Oncology Group criteria is necessary. All patients must have objectively measurable disease either as a measurable lesion or significant biochemical abnormality specific for their tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. No patients from BAMC have been entered on the study during FY 83.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8020 Status: Closed

## TITLE:

Adriamycin + VP-16 vs Adriamycin Alone in Advanced Adenocarcinoma of the Breast, Phase II

|  |  |
|--|--|
| Start Date Jan 81  | Est Comp Date:   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Adenocarcinoma<br>Breast                     |  |

|                               |                               |                             |
|-------------------------------|-------------------------------|-----------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: |
|-------------------------------|-------------------------------|-----------------------------|

Objectives: To determine the efficacy of the Adriamycin and VP-16 combination in the treatment of previously treated patients with disseminated breast cancer, as determined by response-rate compared with Adriamycin alone.

To determine the length of the remission on VP-16 maintenance after an Adriamycin/VP-16 regimen.

Technical Approach: Patients must have histological proof of breast cancer currently Stage IV with measurable lesions. ER+, ER-, and ER unknown patients are eligible. Patient must have adequate cardiac function and no clinical evidence of congestive heart failure.

Therapy will follow the schema outlined in the study protocol.

Progress: There has been no difference in response rates between the two treatment arms. No patients from BAMC are enrolled on this study.

# Detail Summary Sheet

|  |                                  |                |                              |         |         |
|--|----------------------------------|----------------|------------------------------|---------|---------|
| Date:  | 18 Nov 83                        | Proj No:       | SWOG 8024                    | Status: | Ongoing |
| TITLE:   |                                  |                |                              |         |         |
| Combined Modality Therapy for Disseminated Soft Tissue Sarcomas, Phase III |                                  |                |                              |         |         |
| Start Date   | May 81                           | Est Comp Date: | Unknown                      |         |         |
| Principal Investigator   | J. Dean McCracken, M.D., COL, MC |                | Facility                     |         |         |
| Dept/Sec   | Department of Medicine/Oncology  |                | Brooke Army Medical Center   |         |         |
| Key Words:   | Sarcoma                          |                | Associate Investigators:     |         |         |
|  |                                  |                | James F. Boyd, M.D., LTC, MC |         |         |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To compare the effectiveness of bolus administration of Adriamycin and DTIC, to continuous infusion administration of Adriamycin and DTIC, in remission induction of patients with disseminated soft tissue sarcomas.

To compare the toxicities of these two drug schedules.

To determine the feasibility on a group-wide basis of surgical excision of accessible lesions in partially responding patients.

To compare the histology of the diagnostic lesion with the histology of tumor removed from the partial responder.

Technical Approach: Patients with a biopsy confirmed diagnosis of a soft tissue sarcoma with convincing clinical or biopsy-documented evidence of metastatic disease are eligible for this study. Patients must not have received any prior chemotherapy with the agents used in this study. Patients must have a life expectancy of 10 weeks, and all patients must have lesion(s) which is measurable and can be followed for tumor response.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. Therefore, no reportable data are available. No patients from BAMC have been entered into the study during FY 83.



# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8025 Status: Ongoing

## TITLE:

Combination Chemotherapy for Chronic Lymphocytic Leukemia

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 11 May 81                        | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Chronic lymphocytic leukemia     |                          |                              |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To determine the response-rate and duration of remission in patients with CLL treated with combination chemotherapy consisting of Prednisone, Vincristine, Cytosine Arabinoside, Cytosan, and Adriamycin.

To correlate parameters obtained in the clinical, pathological, and immunological staging with response to treatment.

To determine the effect of stopping chemotherapy after patients have achieved a complete remission plus two consolidation courses, in order to define a cured or stabilized fraction of patients.

Technical Approach: All patients who fulfill the criteria for diagnosis of chronic lymphocytic leukemia according to the Rai Classification will be eligible for registration.

Therapy will follow the schema outlined in the study protocol.

Progress: Thus far, nine patients from BAMC have been entered on this study (four during FY 83). Groupwide, 64% of the patients treated with chemotherapy achieved complete + partial responses.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8026 Status: Completed  
 TITLE:

Cis-Platinum in the Treatment of Refractory Epidermoid Carcinoma of the  
 Penis, Phase II

|  |  |
|--|--|
| Start Date Jan 81  | Est Comp Date:   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Epidermoid carcinoma                         |  |

|                               |                               |                             |
|-------------------------------|-------------------------------|-----------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: |
|-------------------------------|-------------------------------|-----------------------------|

Objective: To determine response-rate and survival in patients with advanced  
 epidermoid carcinoma of the penis treated with Cis-platinum.

Technical Approach: Patients must have epidermoid carcinoma of the penis  
 confirmed by biopsy, Stage III or IV, refractory to surgery and radiotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC were entered on this study. Groupwide there  
 was good response to this drug.

Detail Summary Sheet

Date: 18 Nov 83      Proj No: SWOG 8027      Status: Completed

TITLE:

The Natural History of Pathological Stage T<sub>1-2</sub> N<sub>0</sub> M<sub>0</sub> ER+ Breast Cancer, Phase III

|                        |                                  |                              |
|------------------------|----------------------------------|------------------------------|
| Start Date             | 11 May 81                        | Est Comp Date:               |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                     |
| Dept/Sec               | Department of Medicine/Oncology  | Brooke Army Medical Center   |
| Key Words:             | Breast cancer                    | Associate Investigators:     |
|                        |                                  | James F. Boyd, M.D., LTC, MC |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To document recurrence-rates, patterns of recurrence, and survival among patients with Stage I or Stage II node negative (T<sub>1-2</sub> N<sub>0</sub> M<sub>0</sub>) breast cancer whose tumors are determined to be estrogen receptor positive at the time of surgery.

Technical Approach: All female patients having had a radical, modified radical, or adequate local excision, with axillary node dissection for histologically proven breast carcinoma, whose axillary nodes are negative for tumor, and whose estrogen receptor assay on the primary tumor is positive are eligible for this study.

Progress: No data are available.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8030 Status: Ongoing

## TITLE:

Evaluation of DHAD in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase II

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 11 May 81                        | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Squamous cell carcinoma          |                          |                              |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To determine the response-rate and remission duration in patients with advanced squamous cell carcinoma of the head and neck treated with DHAD used in a single dose every-three-week schedule.

To define further the qualitative and quantitative toxicities of DHAD.

Technical Approach: To be eligible for this study, patients must have a verified histologic diagnosis of squamous cell carcinoma of the head and neck region. All patients must have a life expectancy of at least three months.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual continues to be slow. No patients from BAMC have been entered on this study.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8031 Status: Completed

## TITLE:

Evaluation of DHAD in Refractory Multiple Myeloma, Phase II

|  |  |
|--|--|
| Start Date 11 May  | Est Comp Date:   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Multiple myeloma                             |  |

|                               |                               |                             |
|-------------------------------|-------------------------------|-----------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: |
|-------------------------------|-------------------------------|-----------------------------|

Objectives: To determine the response-rate and response duration of patients with refractory multiple myeloma treated with dihydroxyanthracenedione (DHAD) used in a single dose every-three-week schedule.

To define the qualitative and quantitative toxicities of DHAD administered in a Phase II study.

Technical Approach: All patients with multiple myeloma who are not eligible for higher priority Southwest Oncology Group protocols are eligible. Patients must have clearly measurable myeloma protein levels and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC were entered on this study. No reportable data are available.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8032 Status: Closed

## TITLE:

Evaluation of DHAD in Acute Leukemia, Phase II

|  |  |
|--|--|
| Start Date 11 May 81                                       | Est Comp Date:   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Acute leukemia                               |  |

|                               |                               |                             |
|-------------------------------|-------------------------------|-----------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: |
|-------------------------------|-------------------------------|-----------------------------|

Objectives: To determine the efficacy of dihydroxyanthracenedione (DHAD) in patients with adult acute leukemia, who have failed on higher priority treatment protocols, as determined by response-rate and remission duration.

To determine the nature and degree of toxicity of this drug used in a single-dose, every-three-week schedule.

Technical Approach: Eligible patients must have a bone marrow diagnosis of acute leukemia.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC were entered on this study. The study was closed due to poor response to therapy.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8037 Status: Ongoing

## TITLE:

Combined Therapies for Squamous Cell Carcinoma of the Esophagus, Phase II

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 22 May 81                        | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Squamous cell carcinoma          |                          |                              |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To determine the feasibility and toxicity of combined radiotherapy and chemotherapy with 5-fluorouracil and cis-platinum followed by surgery in patients with epidermoid carcinoma of the middle or distal esophagus.

To determine the time to local or distant progression in patients treated by these three combined modalities.

To determine the survival of patients treated by these three combined modalities.

To determine the response-rate by clinical and pathological staging at the time of surgery.

Technical Approach: Previously untreated patients with biopsy-proven squamous cell carcinoma of the middle or distal esophagus are eligible. Patients must be judged medically to be a surgical candidate for laparotomy and thoracotomy. Patients must have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: It is too early for data analysis. Two patients from BAMC have been entered on this study.

# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8038 Status: Ongoing  
 TITLE:

Vinblastine in Advanced Ovarian Cancer, Phase II

|  |  |
|--|--|
| Start Date: 11 May 81                                      | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Ovarian cancer                               |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine the response-rate and remission duration with intra-venous therapy using Velban as a continuous infusion in patients with advanced ovarian cancer.

To define further the qualitative and quantitative toxicity of the continuous infusion of Velban.

Technical Approach: To be eligible, patients must have histologically confirmed, advanced, incurable ovarian cancer who are refractory to or ineligible for treatment on Southwest Oncology Group protocols of higher priority. Patients must have measurable disease and a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide it is too early to evaluate.



# Detail Summary Sheet

Date: 18 Nov 83 Proj No: SWOG 8040 Status: Ongoing

## TITLE:

Evaluation of Combination Chemotherapy (FAM-S) vs a Phase II Drug in Pancreatic Adenocarcinoma, Phase II

|                        |                                  |                              |
|------------------------|----------------------------------|------------------------------|
| Start Date             | 22 May 81                        | Est Comp Date: Unknown       |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                     |
| Dept/Sec               | Department of Medicine/Oncology  | Brooke Army Medical Center   |
| Key Words:             | Pancreatic adenocarcioma         | Associate Investigators:     |
|                        |                                  | James F. Boyd, M.D., LTC, MC |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine the response-rate and survival in patients with advanced pancreatic adenocarcinoma treated with 5-FU, Adriamycin, Mitomycin-C and Streptozotocin (FAM-S).

To determine further the toxicity of the FAM-S regimen.

To determine the activity of a Phase II drug in previously untreated patients with advanced adenocarcinoma of the pancreas by determination of response-rate and duration of response and survival.

To determine further the toxicity of each Phase II agent.

Technical Approach: Patients with histologic confirmation of adenocarcinoma of the exocrine pancreas with distant metastases and/or those with localized disease not amenable to curative surgery or radiotherapy are eligible. All patients must have objectively measurable disease and a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, it is too early to know survival data or to interpret the statistics meaningfully.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8042 Status: Ongoing  
 TITLE:

Evaluation of MGBG in Pancreatic Adenocarcinoma, Phase II

|  |  |
|--|--|
| Start Date '22 May 81                                      | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Pancreatic adenocarcinoma                    |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine the response-rate and its duration in patients with advanced adenocarcinoma of the pancreas treated with MGBG.

To determine the qualitative and quantitative toxicities of MGBG when given on this schedule.

Technical Approach: Patient eligibility is as stated in SWOG 8040.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. No reportable data are available.

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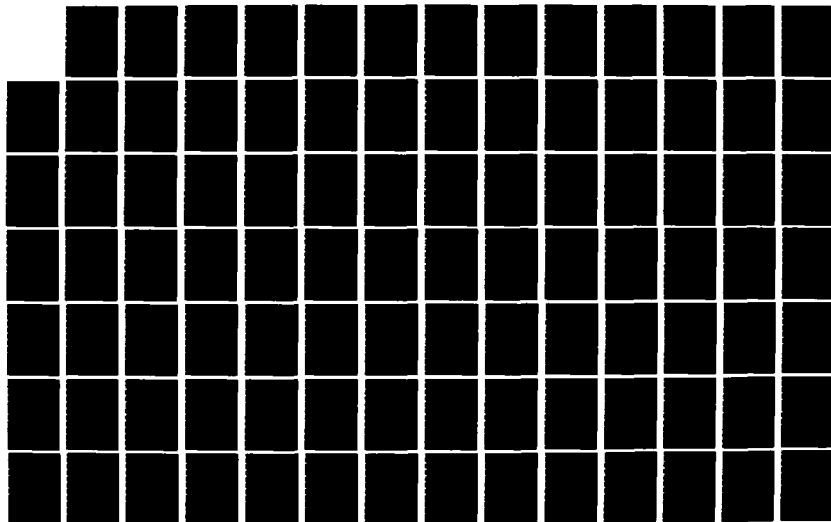
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J H ANDERSON 01 OCT 83

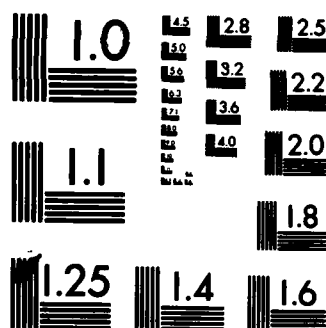
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# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8044 Status: Ongoing

TITLE:

Evaluation of AZQ in Pancreatic Carcinoma, Phase II

Start Date 11 Feb 83 Est Comp Date: Unknown

Principal Investigator  
J. Dean McCracken, M.D., COL, MC

Facility  
Brooke Army Medical Center

Dept/Sec  
Department of Medicine/Oncology

Associate Investigators:  
James F. Boyd, M.D, LTC, MC

Key Words:  
Pancreatic carcinoma  
AZQ

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Periodic  
Review Results:

Objectives: To determine the antitumor activity of AZQ in pancreatic carcinoma.

To further determine the nature and extent of AZQ in a Phase II study.

Technical Approach: Patients with histologic confirmation of adenocarcinoma of the exocrine pancreas with distant metastases and/or those with localized disease not amenable to curative surgery or radiotherapy are eligible. All patients must have objectively measurable disease and a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, no reportable data are available.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8049 Status: Ongoing  
TITLE:

The Treatment of Resected, Poor Risk Prognosis Malignant Melanoma: Stage I: Surgical Excision vs Surgical Excision + Vitamin A, Phase III.

|  |  |
|--|--|
| Start Date: 9 Oct 81                                       | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Malignant melanoma<br>Vitamin A              |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine the efficacy of surgical excision or surgical excision plus vitamin A in preventing the recurrence of high-risk, Stage I malignant melanoma by determination of remission or disease-free interval.

To determine the immunocompetence of patients with malignant melanoma and to determine the influence of vitamin A upon that immunocompetence.

Technical Approach: All patients with a histologically-confirmed diagnosis of high-risk Stage I malignant melanoma who have not been previously treated with chemotherapy, radiation therapy, or immunotherapy are eligible. All patients must have had a wide local excision of the primary lesion.

Therapy will follow the schema outlined in the study protocol.

Progress: No reportable data are available at this time. No patients from BAMC have been entered on this study.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8051 Status: Completed  
 TITLE:

Evaluation of L-Alanosine in Acute Leukemia, Phase II

|                            |                                  |  |
|----------------------------|----------------------------------|--|
| Start Date                 | 25 Sep 81                        | Est Comp Date:   |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC | Facility   |
| Dept/Sec                   | Department of Medicine/Oncology  | Brooke Army Medical Center                               |
| Key Words:                 | Acute leukemia<br>L-Alanosine    | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:       | Periodic Review Results:                                 |

Objectives: To determine the antitumor activity of L-alanosine as determined by response-rate and duration of response in patients with acute leukemia who are not eligible for higher priority studies.

To determine the nature and degree of toxicity of this drug.

Technical Approach: Patients with acute leukemia, either lymphocytic or non-lymphocytic, not eligible for higher priority Southwest Oncology Group studies are eligible. Patients must have at least a 30% cellular marrow and 30% leukemic cells.

Therapy will follow the schema outlined in the study protocol.

Progress: No responses were noted in the evaluable patients. No patients from BAMC were entered on the study.

# Detail Summary Sheet

|   |                              |                          |
|---|------------------------------|--------------------------|
| Date: 21 Nov 83   | Proj No: SWOG 8066           | Status: Completed        |
| TITLE: Adjuvant Intrahepatic Chemotherapy with Mitomycin-C and 5-FU Combined with Hepatic Radiation in High Risk Patients with Carcinoma of the Colon, Phase II-Pilot |                              |                          |
| Start Date Jan 81   | Est Comp Date:               |                          |
| Principal Investigator  | Facility                     |                          |
| J. Dean McCracken, M.D., COL, MC  | Brooke Army Medical Center   |                          |
| Dept/Sec  | Associate Investigators:     |                          |
| Department of Medicine/Oncology   | James F. Boyd, M.D., LTC, MC |                          |
| Key Words:  |                              |                          |
| Carcinoma of Colon  |                              |                          |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:   | Periodic Review Results: |

Objective: To determine the toxicities of combined intra-arterial chemotherapy with hepatic radiotherapy in patients after total clinical resection of cancer of the colon who have a high risk of recurrence, for potential use in adjuvant Group-wide protocol.

Technical Approach: To be eligible, the patient must have adenocarcinoma of the large bowel with involvement of the adjacent regional lymph nodes. There must be no evidence of residual tumor.

Therapy will follow the schema outlined in the study protocol.

Progress: No significant toxicity has been observed. Six patients from BAMC were entered on this study; none during FY 83.



# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8077 Status: Completed  
TITLE:

Combined Chemotherapy and Hormonal Therapy for Recurrent or Disseminated ER+ Breast Cancer, PACT vs ACT, Phase II

|  |  |
|--|--|
| Start Date 9 Oct 81  | Est Comp Date:   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>ER+<br>Hormone Therapy                       |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the response rate of a combined chemo-hormonal program in ER+ patients with metastatic breast cancer.

To determine if the addition of Prednisone will greatly increase the response rate.

Technical Approach: Patients who have histologic evidence of metastatic breast carcinoma are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, no reportable data are available.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8092 Status: Ongoing  
TITLE:

Use of Human Tumor Cloning System to Select Chemotherapy for Patients with Ovarian Cancer Refractory to Primary Therapy, Ancillary Study

|  |  |
|--|--|
| Start Date 11 May 81                                       | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br><br>Human tumor cloning system               |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To utilize the human tumor cloning assay to select single agent chemotherapy for patients with epithelial-type ovarian cancer, refractory to standard therapy.

To determine if the human tumor cloning system can be utilized to select individual patient's therapy in a cooperative group setting.

Technical Approach: Eligible patients must have a pathological diagnosis of epithelial-type ovarian cancer in pleural or peritoneal fluid. Patients should have measurable disease and a life expectancy of at least three months.

Progress: Forty samples have been evaluated for growth. Thirty-one of the samples were in the form of malignant serous, and nine were solid tumors. Of the 40 samples, 14 have shown adequate growth (greater than 30 colonies per dish). Only two of the tumor samples showed less than 30% survival in response to exposure to an anti-cancer drug (DHAD in one sample and m-AMSA in another). There have been too few "sensitive" assays to allow conclusions concerning clinical correlations.

# Detail Summary Sheet

|   |                              |                 |
|---|------------------------------|-----------------|
| Date: 21 Nov 83   | Proj No: SWOG 8093           | Status: Ongoing |
| TITLE: Treatment of Metastatic Malignant Mesothelioma: A Comparison of Cyclophosphamide (Cytosan), DTIC and Adriamycin (CIA) vs Cyclophosphamide and Adriamycin (CA, Phase III) |                              |                 |
| Start Date 9 Oct 81   | Est Comp Date: Unknown       |                 |
| Principal Investigator  | Facility                     |                 |
| J. Dean McCracken, M.D., COL, MC  | Brooke Army Medical Center   |                 |
| Dept/Sec  | Associate Investigators:     |                 |
| Department of Medicine/Oncology   | James F. Boyd, M.D., LTC, MC |                 |
| Key Words:  |                              |                 |
| Mesothelioma  |                              |                 |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine the effect of the drug combination, Cyclophosphamide, DTIC, and Adriamycin vs Cyclophosphamide and Adriamycin (CA) on response-rate, remission duration, and survival of patients with metastatic malignant mesothelioma in a prospective, randomized Phase III clinical trial.

To determine the qualitative and quantitative toxicities of these two drug combinations.

To conduct an epidemiologic survey on all patients designed to identify important environmental factors which may place an individual at risk for the development of malignant mesothelioma.

Technical Approach: All patients must have histologically proven malignant mesothelioma of pleural or peritoneal origin with evidence of distant metastases or documented failure to previous radiation therapy. There must be an expected survival of at least 8 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, no reportable data are available.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8094 Status: Ongoing

## TITLE:

Radiotherapy with and without Chemotherapy for Malignant Mesothelioma  
Localized to One Hemithorax, Phase III

|  |  |
|--|--|
| Start Date 22 May 81                                       | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Mesothelioma                                 |  |

|                               |                               |                                      |
|-------------------------------|-------------------------------|--------------------------------------|
| Accumulative MEDCASE<br>Cost: | Est Accumulative<br>OMA Cost: | Periodic<br>Review Results: Continue |
|-------------------------------|-------------------------------|--------------------------------------|

Objectives: To evaluate in a randomized prospective manner, the efficacy of Adriamycin in improving the disease-free interval in patients who will receive hemithoracic radiotherapy for Stage I pleural mesothelioma.

To further define prospectively the efficacy of radiotherapy to the involved hemithorax in patients with pleural mesothelioma.

Technical Approach: Eligible patients will have histologically confirmed malignant mesothelioma of the pleural cavity. Patients with measurable disease or evaluable disease as well as those in whom all gross disease has been resected will be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Three patients from BAMC have been entered on this study. No data are available at this time.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8101 Status: Completed

## TITLE:

VM-26 in Advanced GU Cancer, Phase II

|                        |                                  |                              |
|------------------------|----------------------------------|------------------------------|
| Start Date             | 9 Oct 81                         | Est Comp Date:               |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                     |
| Dept/Sec               | Department of Medicine/Oncology  | Brooke Army Medical Center   |
| Key Words:             |                                  | Associate Investigators:     |
| GU cancer              |                                  | James F. Boyd, M.D., LTC, MC |
| VM-26                  |                                  |                              |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the response-rate and duration of response of VM-26 in locally advanced or metastatic transitional cell carcinoma of the bladder, ureter, renal pelvis, and renal cell carcinoma.

To determine further the quantitative and qualitative toxicity in patients treated with VM-26.

Technical Approach: All patients not eligible for higher priority Southwest Oncology Group protocols, with histologically proven, incurable, advanced or metastatic, transitional cell carcinoma of the bladder, ureter or renal pelvis and renal cell carcinoma are eligible. There are no age restrictions. Patients must have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient from BAMC was registered on this study (none during FY 83). There was no response, and the patient was subsequently treated on a higher priority protocol. No reportable data are available from the Southwest Oncology Group.

# Detail Summary Sheet

|   |  |                          |                          |                              |         |
|---|--|--------------------------|--------------------------|------------------------------|---------|
| Date:   | 21 Nov 83                                | Proj No:                 | SWOG 8102                | Status:                      | Ongoing |
| TITLE:  |  |                          |                          |                              |         |
| Whole Brain Irradiation and Intrathecal Methotrexate in the Treatment of Solid Tumors Leptomeningeal Metastases, Phase II |  |                          |                          |                              |         |
| Start Date  | 12 Feb 82                                | Est Comp Date:           | Unknown                  |                              |         |
| Principal Investigator  | J. Dean McCracken, M.D., COL, MC         |                          | Facility                 | Brooke Army Medical Center   |         |
| Dept/Sec  | Department of Medicine/Oncology          |                          | Associate Investigators: | James F. Boyd, M.D., LTC, MC |         |
| Key Words:  | Leptomeningeal metastases<br>Solid Tumor |                          |                          |                              |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:               | Periodic Review Results: | Continue                 |                              |         |

Objective: To determine the response-rate (CR + PR) of intrathecal methotrexate and whole brain irradiation in the control of solid tumor leptomeningeal metastases.

Technical Approach: All patients must have cerebrospinal fluid which is cytologically positive for malignant cells.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been enrolled on this study. No reportable data are available from the Southwest Oncology Group.

# Detail Summary Sheet

|   |   |                          |                          |                              |         |
|---|---|--------------------------|--------------------------|------------------------------|---------|
| Date:   | 21 Nov 83                                     | Proj No:                 | SWOG 8104                | Status:                      | Ongoing |
| TITLE:  |   |                          |                          |                              |         |
| Treatment of Advanced Seminoma (Stage cII (N <sub>4</sub> ) + cIII) with Combined Chemotherapy and Radiation Therapy, Phase II.   |   |                          |                          |                              |         |
| Start Date  | May 82  | Est Comp Date:           | Unknown                  |                              |         |
| Principal Investigator  | J. Dean McCracken, M.D., COL, MC              |                          | Facility                 | Brooke Army Medical Center   |         |
| Dept/Sec  | Department of Medicine/Oncology               |                          | Associate Investigators: | James F. Boyd, M.D., LTC, MC |         |
| Key Words:  | Seminoma<br>Chemotherapy<br>Radiation Therapy |                          |                          |                              |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:                    | Periodic Review Results: | Continue                 |                              |         |
| Objective: To determine the response-rate and survival patterns in patients with advanced seminoma (Stage cII (N <sub>4</sub> ) + cIII) treated with combined chemotherapy and radiation therapy. |   |                          |                          |                              |         |

Technical Approach: All patients with histologically proven, Stage cII (N<sub>4</sub>) and cIII, advanced, pure or anaplastic testicular seminoma who have had no prior chemotherapy or radiation therapy are eligible. Patients must have no other evidence of malignant disease.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient from BAMC was enrolled on this study during FY 83. It is too early to draw any definite conclusions.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8106 Status: Ongoing

## TITLE:

Evaluation of AZQ (Carbamic Acid) in Central Nervous System Tumors, Phase II

Start Date 12 Feb 82 Est Comp Date: Unknown

Principal Investigator Facility

J. Dean McCracken, M.D., COL, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Medicine/Oncology James F. Boyd, M.D., LTC, MC

## Key Words:

Carbamic Acid (AZQ)

Central Nervous System Tumors

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine the efficacy of AZQ given by intermittent bolus schedule in malignant gliomas by evaluation of response-rate, duration and survival.

To determine the qualitative and quantitative toxicities of AZQ given by this schedule in a Phase II setting.

Technical Approach: To be eligible patients must have a histologically-confirmed diagnosis of astrocytoma, Grades III and IV; ependymoblastoma; medulloblastoma; or oligodendroglioma. Patients must have failed primary surgical and/or radiation therapies and not be eligible for higher priority protocols. All patients should have received adequate prior radiotherapy. Patients must have a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC were entered on this study during FY 83. Groupwide, no reportable data are available.



# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8107 Status: Ongoing

## TITLE:

Management of Disseminated Melanoma, Master Protocol, Phase II-III

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 9 Jul 82                         | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Melanoma                         |                          |                              |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objective: To determine the effectiveness of cranial irradiation given electively in disseminated melanoma patients with lung and/or liver metastases to prevent or delay the clinical appearance of brain metastases.

Technical Approach: Patients should have histologic proof of melanoma and a negative radiographic study of the brain. Patients must have established disseminated melanoma with lung and/or liver metastases.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient from BAMC has been entered on this study. Groupwide, no reportable data are available at this time.

# Detail Summary Sheet

|   |  |                          |  |         |         |
|---|--|--------------------------|--|---------|---------|
| Date:   | 21 Nov 83                                    | Proj No:                 | SWOG 8108  | Status: | Ongoing |
| TITLE:  |  |                          |  |         |         |
| Evaluation of Bisantrene Hydrochloride in Refractory Multiple Myeloma, Phase II |  |                          |  |         |         |
| Start Date  | 14 May 82                                    | Est Comp Date:           | Unknown  |         |         |
| Principal Investigator  | J. Dean McCracken, M.D., COL, MC             |                          | Facility   |         |         |
| Dept/Sec  | Department of Medicine/Oncology              |                          | Brooke Army Medical Center                               |         |         |
| Key Words:  | Multiple myeloma<br>Bisantrene hydrochloride |                          | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:                   | Periodic Review Results: | Continue   |         |         |

Objectives: To determine the response rate and response duration of refractory multiple myeloma treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of multiple myeloma. Bisantrene hydrochloride is intended for therapy of patients with multiple myeloma who have had prior exposure to, and progression of disease on, protocols of higher priority.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, it is too early to report any meaningful results.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8110 Status: Ongoing

## TITLE:

Treatment of Advanced Germ Cell neoplasms of the Testis: A Comparison of Remission Induction...vs Observation, Phase III

|  |  |
|--|--|
| Start Date: Jun 82   | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Germ cell neoplasm                           |  |

|                            |                            |                                    |
|----------------------------|----------------------------|------------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continued |
|----------------------------|----------------------------|------------------------------------|

Objectives: To compare in a randomized fashion the effectiveness of the drug combination Vinblastine, Cis-platinum, and VP 16-213 vs Vinblastine, Bleomycin and Cis-platinum in the remission induction of patients with disseminated germ cell neoplasms of testicular origin.

To determine the role of six months maintenance chemotherapy vs observation for those patients who achieve a complete response during induction, or have a totally resected mature teratoma, in terms of relapse-free survival and overall survival.

To determine the role of six months of maintenance chemotherapy vs observation for those patients with residual carcinoma having no evidence of disease following surgery, in terms of relapse-free survival and overall survival.

To document the nature and extent of the hematologic and non-hematologic side effects of the treatment modalities.

Technical Approach: Patients should have a histologically confirmed diagnosis of disseminated germ cell neoplasms of testicular origin. All patients with bulky abdominal disease (Stage cII(N<sub>4</sub>) or Stage cIII) will be eligible for the study. Patients should have an expected survival of at least eight weeks.

Progress: Three patients from BAMC have been entered on this study. It is too early to report any significant results.

# Detail Summary Sheet

|  |  |                 |
|--|--|-----------------|
| Date: 22 Nov 83  | Proj No: SWOG 8111                                       | Status: Ongoing |
| TITLE: The Treatment of Resected, Poor Prognosis Malignant Melanoma: Stage II - Surgical Excision vs Surgical Excision + Vitamin A vs Surgical Excision + Actinomycin D and DTIC |  |                 |
| Start Date 13 May 83   | Est Comp Date: Unknown                                   |                 |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC   | Facility<br>Brooke Army Medical Center                   |                 |
| Dept/Sec<br>Department of Medicine/Oncology  | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |                 |
| Key Words:<br>Malignant melanoma   |  |                 |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine the efficacy of surgical excision plus vitamin A, and surgical excision plus combination chemotherapy (Actinomycin-D and DTIC) in preventing the recurrence of Stage II malignant melanoma by the determination of remission duration or disease-free interval.

Technical Approach: All patients must have a histologically confirmed diagnosis of lymph node melanoma and complete and adequate surgical excision of all residual disease. Patients with completely resected mucosal melanoma or first recurrence will be eligible, but will be stratified separately at the time of registration. All patients must be randomized and treatment begun within six weeks of the lymph node dissection.

Progress: This is a new study. No patients from BAMC have been enrolled on this study.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8112 Status: Closed  
 TITLE:

Combination Chemotherapy of Unfavorable Histology Non-Hodgkin's  
 Lymphoma with CHOP and CVB, Phase II.

|                                  |                              |
|----------------------------------|------------------------------|
| Start Date 13 Mar 82             | Est Comp Date:               |
| Principal Investigator           | Facility                     |
| J. Dean McCracken, M.D., COL, MC | Brooke Army Medical Center   |
| Dept/Sec                         | Associate Investigators:     |
| Department of Medicine/Oncology  | James F. Boyd, M.D., LTC, MC |
| Key Words:                       |                              |
| Non-Hodgkin's lymphoma           |                              |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To gain experience with a treatment program utilizing a combination of two non-cross resistant drug regimens in the treatment of "poor prognosis" lymphomas.

To determine an approximate complete remission rate to the Cyclophosphamide, Adriamycin, Vincristine, and Prednisone (CHOP)/Cis-platinum, Vinblastine, and Bleomycin (CVB) treatment program prior to initiating a group-wide Phase III study utilizing this program.

Technical Approach: Biopsy proven previously untreated patients with Stage II-IV non-Hodgkin's lymphoma, "poor prognosis" histology will be eligible for treatment with this regimen. No prior chemotherapy with a single agent or combined chemotherapy is allowed.

Progress: This study has been closed to new entries. No patients from BAMC remain on the study.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8116 Status: Ongoing

## TITLE:

Evaluation of Bisantrene Hydrochloride in Refractory Lymphoma, Phase II

|                            |  |                          |                              |
|----------------------------|--|--------------------------|------------------------------|
| Start Date                 | 9 Apr 82   | Est Comp Date:           | Unknown                      |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC                 | Facility                 | Brooke Army Medical Center   |
| Dept/Sec                   | Department of Medicine/Oncology                  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | Lymphoma, refractory<br>Bisantrene hydrochloride |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:                       | Periodic Review Results: | Continue                     |

Objectives: To determine the response rate and response duration of malignant lymphoma treated with bisantrene hydrochloride used in a single dose, every three-week shcedule.

To define the qualitative and quantitative toxicities of bisantrene hydrochloride administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of malignant lymphoma. Bisantrene is intended for therapy of patients with refractory lymphomas who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have evaluable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient from BAMC has been entered on this study. No reportable data are available at this time.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8117 Status: Closed  
 TITLE:

Evaluation of Bisantrene Hydrochloride in Refractory Ovarian Cancer,  
 Phase II

|                            |  |  |
|----------------------------|--|--|
| Start Date                 | 9 Apr 82                                   | Est Comp Date:   |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC           | Facility   |
| Dept/Sec                   | Department of Medicine/Oncology            | Brooke Army Medical Center                               |
| Key Words:                 | Ovarian cancer<br>Bisantrene hydrochloride | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:                 | Periodic Review Results:                                 |

Objectives: To determine response rate and response duration of refractory ovarian cancer treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of ovarian cancer. Bisantrene is intended as therapy of patients with ovarian cancer who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have evaluable disease. Patients must not be receiving concomitant radiation therapy, hormonal therapy, or other chemotherapy while on this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC were entered on this study. Groupwide, no reportable data are available.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8118 Status: Ongoing

## TITLE:

Evaluation of Bisantrene Hydrochloride in Refractory Malignant Melanoma, Phase II

|  |  |
|--|--|
| Start Date 9 Apr 82  | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Malignant melanoma                           |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine the response rate and response duration of malignant melanoma treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of melanoma. Bisantrene is intended for therapy of patients who have had prior exposure to, and progression of disease on, protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient from BAMC has been entered on this study. It is too early to report any meaningful results.



# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8119 Status: Ongoing

## TITLE:

Evaluation of Bisantrene Hydrochloride in Hepatoma

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 9 Apr 82                         | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Hepatoma                         |                          |                              |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To determine the response rate and response duration of hepatomas treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II Study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of hepatoma. Bisantrene is intended as therapy of patients with extensive disease or those patients not eligible or relapsing on protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, no reportable data are available.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8120 Status: Ongoing

## TITLE:

Evaluation of Bisantrene Hydrochloride in Gastric Carcinoma, Phase II

|  |  |
|--|--|
| Start Date 9 Apr 82  | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Gastric carcinoma                            |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine the response rate, response duration, and duration of survival of gastric carcinoma patients treated with bisantrene hydrochloride used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene hydrochloride administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of adenocarcinoma of the stomach with gross unresectable residual disease. Bisantrene is intended for therapy of patients with gastric carcinoma not eligible for protocols of higher priority and patients relapsing on protocols of higher priority. Patients must have measurable disease.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient from BAMC was enrolled on this study during FY 83. Groupwide, no reportable data are available.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8122 Status: Ongoing

## TITLE:

Combined Modality Treatment of Extensive Small Cell Lung Cancer, Phase III

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 14 May 82                        | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Small cell lung cancer           |                          |                              |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To compare the response rate and duration of a new induction program (multiple alkylating agents plus Vincristine), with emphasis on complete response, to the combination of Vincristine, Adriamycin and Cyclophosphamide in the treatment of extensive small cell lung cancer.

To examine the effect of radiation consolidation on relapse in the chest and liver in patients without widespread skeletal disease.

To assess qualitative and quantitative toxicity of this combined modality approach.

To perform a prospective analysis, by electron microscopy, of the available material for clinicopathologic correlation.

To evaluate the effectiveness of a more aggressive radiation therapy approach to clinically evident brain metastases.

To evaluate the impact of chest radiation therapy following relapse as to the duration of response and survival.

To improve survival and the quality of life in patients with extensive small cell lung cancer.

Technical Approach: All patients with extensive small cell carcinoma of the lung (spread of disease beyond the ipsilateral hemithorax and its regional nodal drainage) are eligible for entry onto this study. Patients must not have had prior treatment with chemotherapy or radiation therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Five patients from BAMC have been entered on this study. It is too early to evaluate.

# Detail Summary Sheet

|   |                            |  |  |                 |
|---|----------------------------|--|--|-----------------|
| Date: 22 Nov 83   |                            | Proj No: SWOG 8124/5/6                                   |  | Status: Ongoing |
| TITLE: Treatment of Acute Non-Lymphocytic Leukemia with Conventional Induction, Consolidation Chemotherapy: Maintenance with Chemotherapy vs Bone Marrow Transplantation Following Total Body Irradiation, Phase III  |                            |  |  |                 |
| Start Date 12 Nov 82  |                            | Est Comp Date: Unknown                                   |  |                 |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC  |                            | Facility<br>Brooke Army Medical Center                   |  |                 |
| Dept/Sec<br>Department of Medicine/Oncology   |                            | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |  |                 |
| Key Words:<br>Acute non-lymphocytic leukemia  |                            |  |  |                 |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results:                                 |  |                 |
| Objectives: To determine the complete remission-rate with intensive induction chemotherapy in patients with acute non-lymphocytic leukemia, focusing attention on those patients over 50 years of age.  |                            |  |  |                 |
| To compare duration of remission and survival of patients receiving maintenance with or without intensification chemotherapy versus those patients receiving an HLA identical sibling bone marrow transplant while in first remission.  |                            |  |  |                 |
| To determine the comparative toxicity of these regimens.  |                            |  |  |                 |
| To compare the continuous maintenance therapy and late intensification with late intensification alone.   |                            |  |  |                 |
| Evaluate the prognostic significance of any chromosome abnormalities in leukemic cell lines.  |                            |  |  |                 |
| Technical Approach: All patients with a diagnosis of acute non-lymphocytic leukemia who have not received prior therapy and who do not have initial CNS leukemia will be eligible for this study. There are no age restrictions; however, patients over the age of 50 will not be considered for bone marrow transplantation. |                            |  |  |                 |
| Progress: This is a new study. No patients from BAMC have been entered.   |                            |  |  |                 |

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8161 Status: Ongoing

## TITLE:

Evaluation of Bisantrene Hydrochloride in Adult Acute Leukemia, Phase II - Pilot

|                        |                                  |                          |   |
|------------------------|----------------------------------|--------------------------|---|
| Start Date             | 9 Apr 82                         | Est Comp Date:           | Unknown   |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center                                    |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC<br>Glenn M. Mills, M.D., MAJ, MC |
| Key Words:             | Acute Leukemia                   |                          |   |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To determine the response rate and response duration of adult acute leukemia treated with bisantrene hydrochloride.

To define the qualitative and quantitative toxicities of bisantrene when administered daily for five days every three weeks.

Technical Approach: All patients must have pathologically verified histologic diagnosis of adult acute leukemia. The diagnosis of adult acute leukemia will be made by bone marrow smear and an absolute infiltrate of 50% leukemic cells or greater. Bisantrene is intended for therapy of patients with adult acute leukemia in relapse who have had prior exposure to, and progression of disease, on, protocols of higher priority. Patients must not be receiving concomitant chemotherapy while on this protocol.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient was entered on this study during FY 83. It is too early to report any responses.

# Detail Summary Sheet

|  |                                  |                |                          |                              |         |
|--|----------------------------------|----------------|--------------------------|------------------------------|---------|
| Date:  | 21 Nov 83                        | Proj No:       | SWOG 8200                | Status:                      | Ongoing |
| TITLE:   |                                  |                |                          |                              |         |
| Evaluation of Vinblastine by Continuous Infusion for Advanced, Recurrent Endometrial Carcinoma, Phase II |                                  |                |                          |                              |         |
| Start Date   | 14 May 82                        | Est Comp Date: | Unknown                  |                              |         |
| Principal Investigator   | J. Dean McCracken, M.D., COL, MC |                | Facility                 | Brooke Army Medical Center   |         |
| Dept/Sec   | Department of Medicine/Oncology  |                | Associate Investigators: | James F. Boyd, M.D., LTC, MC |         |
| Key Words:   | Endometrial carcinoma            |                |                          |                              |         |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objective: To evaluate the efficacy of a five day vinblastine infusion with respect to remission induction, remission duration, and survival duration in patients with advanced, recurrent, or Stages III and IV endometrial carcinoma refractory to prior chemotherapy.

Technical Approach: Patients with pathologically proven adenocarcinoma or adenosquamous carcinoma of the endometrium who have recurrent disease, or Stage III or IV disease no longer treatable with radiation therapy or surgery, are eligible. Patients must not have received prior chemotherapy with vinca alkaloids. Patients may have had previous chemotherapy of other types. Patients must have clinically measurable disease either by radiologic techniques or physical examination.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, no reportable data are available.

# Detail Summary Sheet

|  |  |                          |
|--|--|--------------------------|
| Date: 21 Nov 83  | Proj No: SWOG 8203/04                                    | Status: Ongoing          |
| TITLE: Randomized Comparison of Adriamycin, Mitoxantrone and Bisantrone in Patients with Metastatic Breast Cancer not Previously Exposed to Intercalating Chemotherapy, Phase III. |  |                          |
| Start Date 10 Dec 82   | Est Comp Date: Unknown                                   |                          |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC   | Facility<br>Brooke Army Medical Center                   |                          |
| Dept/Sec<br>Department of Medicine/Oncology  | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |                          |
| Key Words:<br>Metastatic breast cancer<br>Intercalating chemotherapy   |  |                          |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:                               | Periodic Review Results: |

Objectives: To determine the comparative response rate, duration of response, and survival of equimyelosuppressive doses of Adriamycin, Mitoxantrone, and Bisantrone as single agents in breast cancer patients, not previously exposed to an intercalating agent, using a single dose, every-three-week regimen.

To determine the salvage response rate of Adriamycin, Mitoxantrone, or Bisantrone in breast cancer patients failing one of these three agents.

To assess the cardiotoxicity of Adriamycin, Mitoxantrone, and Bisantrone as determined by history, physical examination, and measurement of the left ventricular ejection fraction.

To compare the relative noncardiac toxicities of the three agents.

Technical Approach: Patients must have a pathologically verified diagnosis of breast cancer in order to be eligible for this study. Patients must have objectively measurable or evaluable lesion(s) excluding CNS metastases. Patients must not have been previously treated with Adriamycin, Mitoxantrone, or Bisantrone, but must have had only one prior chemotherapy regimen as adjuvant therapy.

Therapy will follow the schema outlined in the study protocol.

Progress: Three patients from BAMC have been entered on this study. No report-data are available at this time.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8206 Status: Closed

## TITLE:

Evaluation of Aclacinomycin-A in Colorectal Carcinoma, Phase II

|                            |   |  |
|----------------------------|---|--|
| Start Date                 | 9 Jul 82                                | Est Comp Date:   |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC        | Facility   |
| Dept/Sec                   | Department of Medicine/Oncology         | Brooke Army Medical Center                               |
| Key Words:                 | Colorectal carcinoma<br>Aclacinomycin-A | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:              | Periodic Review Results:                                 |

Objectives: To determine the antitumor activity of Aclacinomycin A in previously untreated patients with colorectal carcinoma by determination of the response-rate and remission duration of two dosage schedules; a single dose, every three-week schedule and a weekly dosage schedule for four weeks out of six.

To further define the qualitative and quantitative toxicities of this drug for each of the two dosage schedules in a Phase II study.

Technical Approach: Patients must have biopsy proven adenocarcinoma arising from the colon or rectum. They must have clinically measurable recurrent or disseminated disease to qualify for the study. Patients must be equal to or less than 65 years old, have a life expectancy of at least ten weeks and a performance status of at worst Grade 2 by Southwest Oncology Group criteria.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC were entered on this study. Groupwide no data are available.



# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8207 Status: Ongoing

## TITLE:

AZQ in Advanced Renal Cell Carcinoma, Phase II

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 10 Sep 82                        | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Renal cell carcinoma             |                          |                              |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To determine the response rate and duration of response in patients with advanced renal cell carcinoma treated with AZQ used in a single dose, every three-week schedule.

To define the qualitative and quantitative toxicities of AZQ administered in a Phase II study.

Technical Approach: All patients with a diagnosis of histologically proven, advanced renal cell carcinoma not eligible for higher priority Southwest Oncology Group protocols are eligible. Patients must have clearly measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients from BAMC have been entered on this study. Groupwide, no reportable data are available.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8208 Status: Ongoing

## TITLE:

Trial of Chlorozotocin and 5-FU in Metastatic Islet Cell Carcinoma,  
Phase II

Start Date 11 Mar 83 Est Comp Date: Unknown

Principal Investigator J. Dean McCracken, M.D., COL, MC Facility  
Brooke Army Medical Center

Dept/Sec Department of Medicine/Oncology Associate Investigators:  
James F. Boyd, M.D., LTC, MC

Key Words: Islet cell carcinoma

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|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To study the response of functioning and non-functioning islet cell carcinoma to chlorozotocin (CTZ) and 5-fluorouracil (5-FU).

To determine the toxicity of 5-FU and CTZ when given in combination.

Technical Approach: To be eligible for this study, all patients must have biopsy-proven islet cell carcinoma not amenable to further surgical therapy; and a minimum life expectancy of greater than six weeks. All patients must have objectively measurable disease, or a significant biochemical abnormality secondary to endocrine hyperfunction specific for their islet cell tumors.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients from BAMC have been entered on this study.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8209 Status: Ongoing  
TITLE:

A Study of AZQ (Aziridinybenzoquinone) in Soft Tissue and Bony Sarcomas, Phase II.

|  |  |
|--|--|
| Start Date 10 Dec 82                                       | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Soft tissue sarcomas<br>Bony sarcomas        |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the antitumor activity of Aziridinybenzoquinone (AZQ) in soft tissue and bony sarcomas by determination of the response rate and the remission duration.

To further determine the nature and extent of Aziridinybenzoquinone toxicity in a Phase II study.

Technical Approach: Eligible patients must have histologically proven advanced soft tissue and bony sarcomas, not amenable to surgery or treatment with Southwest Oncology Group Studies of higher priority. Patients must have a life expectancy of six weeks or more and a performance status of 2 or better. They must not have had prior chemotherapy or radiation therapy within three weeks and recovery must have occurred from the acute toxicities of these treatments.

Therapy will follow the schema outlined in the study protocol.

Progress: Patient accrual has been slow. No reportable data are available.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: SWOG 8210 Status: Ongoing

## TITLE:

A Comparison of Aggressive Radiotherapy + Chemotherapy vs Aggressive Chemotherapy in the Treatment of Limited Carcinoma of the Pancreas, Phase III

Start Date 12 Nov 82 Est Comp Date: Unknown

Principal Investigator J. Dean McCracken, M.D., COL, MC Facility Brooke Army Medical Center

Dept/Sec Department of Medicine/Oncology Associate Investigators: James F. Boyd, M.D., LTC, MC

Key Words: Carcinoma of pancreas

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|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine whether aggressive therapy with combination radiotherapy/chemotherapy or chemotherapy alone yields superior survival in patients with incurable localized pancreatic cancer.

To compare the toxicities of the two programs.

Technical Approach: Surgical exploration is required to establish truly unresectable localized disease. Patients must have a histological confirmation of adenocarcinoma of the exocrine pancreas. Patients must have a life expectancy of at least 10 weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: Three patients have been entered on this study. No significant reportable data are available at this time.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: SWOG 8211 Status: Ongoing

## TITLE:

Evaluation of Cis-Diamminedichloroplatinum in Disseminated Gastric Adenocarcinoma, Phase II

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 8 Oct 82                         | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Gastric adenocarcinoma           |                          |                              |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To test the response-rate of cis-diamminedichloroplatinum (DDP) in patients with disseminated and measurable adenocarcinoma of the stomach who are previously untreated.

To test the response-rate of cis-diamminedichloroplatinum in patients with disseminated adenocarcinoma of the stomach who are previously treated with 5-fluorouracil, Adriamycin, and Mitomycin-C (5-FAM) chemotherapy.

Technical Approach: Eligible patients must have a histologically proven gastric adenocarcinoma and be considered inoperable for cure at the time of entry on the study. Patients must have a life expectancy of six weeks or longer.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient from BAMC has been entered on this study. It is too early to report any significant response.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8213 Status: Closed

TITLE:

Evaluation of Aclacinomycin-A in Refractory Multiple Myeloma, Phase II

|                        |                                  |                              |
|------------------------|----------------------------------|------------------------------|
| Start Date             | 10 Sep 82                        | Est Comp Date:               |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                     |
| Dept/Sec               | Department of Medicine/Oncology  | Brooke Army Medical Center   |
| Key Words:             | Multiple myeloma                 | Associate Investigators:     |
|                        |                                  | James F. Boyd, M.D., LTC, MC |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine the response rate and duration of remission of Aclacinomycin A used in a weekly schedule (followed by two weeks rest) for patients with refractory multiple myeloma.

Technical Approach: All patients with histologically confirmed multiple myeloma, refractory to initial therapy, who are not eligible for higher priority Southwest Oncology Group protocols are eligible. Patients must have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed because of poor response.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: SWOG 8214 Status: Ongoing

## TITLE:

Evaluation of Bisanrene Hydrochloride in Advanced Sarcoma, Phase II

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 12 Nov 82                        | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Sarcoma                          |                          |                              |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the response rate and response duration of advanced sarcoma treated with bisantrene hydrochloride used in a single dose, every-three-week schedule.

To define the qualitative and quantitative toxicities of bisantrene administered in a Phase II study.

Technical Approach: All patients must have a pathologically verified histologic diagnosis of sarcoma. Every effort should be made to include patients who have not been treated with more than one prior chemotherapy regimen and also to admit those patients with no prior chemotherapy who do not otherwise qualify for higher priority Southwest Oncology Group protocols.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients from BAMC have been entered on the protocol.

# Detail Summary Sheet

|   |  |                 |
|---|--|-----------------|
| Date: 22 Nov 83   | Proj No: SWOG 8215                                       | Status: Ongoing |
| TITLE: Comparison of Combination Chemotherapy with VP-16 and Cis-Platinum vs BCNU, Thiotepa, Vincristine and Cyclophosphamide in Patients with Small Cell Carcinoma of the Lung Who Have Failed or Relapsed Primary Chemotherapy, Phase 3 |  |                 |
| Start Date 8 Jul 83   | Est Comp Date: Unknown                                   |                 |
| Principal Investigator<br>J. Dean McCracken, M.D, COL, MC   | Facility<br>Brooke Army Medical Center                   |                 |
| Dept/Sec<br>Department of Medicine/Oncology   | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |                 |
| Key Words:<br>Small cell lung carcinoma   |  |                 |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To confirm the efficacy of combination VP-16-213 (VP-16) and Cis-diamminedichloroplatinum (Cis-Platinum) in the treatment of patients with small cell carcinoma of the lung who have failed or relapsed on first-line treatment protocols. |                            |                          |

Through a randomized trial, to compare the remission rate, duration of remission, and toxicity between the combination of VP-16 plus Cis-Platinum and the combination of bis-chloroethylnitrosourea (BCNU), triethylenethiophosphoramide (Thiotepa), Vincristine (Oncovin) and Cyclophosphamide (Cytosan) in the same group of patients.

Technical Approach: For inclusion in the study, patients must have a histologically proven diagnosis of small cell carcinoma of the lung and documented relapse or progression following prior therapy. Patients must have had prior chemotherapy. All patients who have relapsed on first-line Southwest Oncology Group protocols for either extensive disease or limited disease, or who have had prior chemotherapy with other induction studies are eligible. Patients may have had prior treatment with any of the agents used in this study, but not with either of the two combinations to be employed. All patients must have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients from BAMC have been enrolled on this protocol.



# Detail Summary Sheet

Date: 22 Nov 83 Proj No: SWOG 8217 Status: Ongoing

TITLE: Evaluation of Spirogermanium in Adenocarcinoma of the Prostate, Phase II

|                            |                                  |                          |                              |
|----------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date                 | 8 Oct 82                         | Est Comp Date:           | Unknown                      |
| Principal Investigator     | J. Dean McCracken, M.C., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec                   | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | Adenocarcinoma of prostate       |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:       | Periodic Review Results: |                              |

Objectives: To determine the response rate and remission duration of adenocarcinoma of the prostate when treated with Spirogermanium, used as a 60 minute infusion in a three times weekly schedule.

To define the qualitative and quantitative toxicities of Spirogermanium administered in a Phase II study.

Technical Approach: All patients must have a histologically proven diagnosis of adenocarcinoma of the prostate. They must have evaluable or measurable disease and a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients from BAMC have been enrolled.

# Detail Summary Sheet

Date: 21 Nov 83 Proj No: SWOG 8218 Status: Closed

## TITLE:

Evaluation of Spirogermanium (NSC-192965) in Renal Cell Carcinoma, Phase II

|  |  |
|--|--|
| Start Date 10 Sep 82   | Est Comp Date:   |
| Principal Investigator ,<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                  | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Renal cell carcinoma<br>Spirogermanium         |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the response rate and remission duration of renal cell carcinoma when treated with Spirogermanium, used as a 60 minute infusion in a three times weekly schedule.

To define the qualitative and quantitative toxicities of Spirogermanium administered as a Phase II study.

Technical Approach: All patients must have a histologically proven diagnosis of renal cell carcinoma, and not be eligible for Southwest Oncology Group protocols of higher priority. Patients must have a clearly measurable disease. Patients should have a life expectancy of at least six weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This study was closed because of poor patient accrual.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: SWOG 8219 Status: Ongoing

TITLE:

Evaluation of Combined or Sequential Chemo-Endocrine Therapy in Treatment of Advanced Adenocarcinoma of the Prostate, Phase III

Start Date 12 Nov 82 Est Comp Date: Unknown

Principal Investigator Facility

J. Dean McCracken, M.D., COL, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Medicine/Oncology James F. Boyd, M.D., LTC, MC

Key Words:

Adenocarcinoma of prostate

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To compare the efficacy of the sequential use of endocrine therapy followed at the time of progression by cytotoxic chemotherapy (Adriamycin and cyclophosphamide) versus the combination of endocrine therapy and chemotherapy together in the treatment of advanced adenocarcinoma of the prostate by determination of the response rate, response duration, and duration of survival.

Technical Approach: All patients with histologically proven, asymptomatic or symptomatic Stage D adenocarcinoma of the prostate are eligible. Patients may not have had previous hormonal therapy or chemotherapy. They should have a life expectancy of 6 weeks or greater.

Therapy will follow the schema outlined in the study protocol.

Progress: Five patients have been entered on this study. It is too early to report any positive or negative responses.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: SWOG 8223-5 Status: Ongoing  
TITLE:

Master Protocol: Randomized Comparison of Drug Therapy for Squamous Cell Cancer of the Head and Neck with Early Assessment Phase II Agents, Phase III

|  |  |
|--|--|
| Start Date 12 Nov 82                                       | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Squamous cell cancer of head<br>and neck     |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To estimate and compare response rates produced by the two combination regimens Arm I vs Arm II in all patients who receive either regimen (either at initial randomization or after re-randomization subsequent to failure on Arm III).

To estimate and compare response rates for those patients who receive either of the two combination regimens at initial randomization vs those patients who receive either of the two combination regimens after failure on Arm III. (The purpose of this comparison is to determine whether first use of Phase II agents alters patients' subsequent chances for remission induced by drugs of known activity.

To characterize toxicity experience on treatment Arms I, II, and for each agent in Arm III by type, severity, and frequency.

To characterize and compare survival experience for the groups described above.

Technical Approach: Patients must have a histologically proven advanced squamous cell carcinoma of the head and neck region which is not curable by other forms of therapy. They must have an objectively measurable tumor lesion(s) and a life expectancy of eight weeks or greater.

Progress: This is a new study. No patients from BAMC have been enrolled.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: SWOG 8228 Status: Ongoing

## TITLE:

Correlation Between Progesterone Receptor and Response to Tamoxifen in Patients with Newly Diagnosed Metastatic Breast Disease, Phase II

Start Date 12 Nov 82 Est Comp Date: Unknown

Principal Investigator J. Dean McCracken, M.D., COL, MC Facility Brooke Army Medical Center

Dept/Sec Department of Medicine/Oncology Associate Investigators: James F. Boyd, M.D., LTC, MC

Key Words:  
Tamoxifen  
Breast disease

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To define the prognostic role of progesterone receptor in patients with newly diagnosed metastatic breast disease by correlating progesterone receptor levels with objective response rates in women treated with Tamoxifen.

Technical Approach: Female patients who have new, metastatic breast carcinoma are eligible for this study. Patients who have received prior hormonal adjuvant therapy are eligible, provided that they have not failed during therapy and the therapy has been stopped for at least three months. Patients must be ER+ in order to be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients from BAMC have been entered on this protocol.

# Detail Summary Sheet

|   |                            |                          |  |         |         |
|---|----------------------------|--------------------------|--|---------|---------|
| Date:   | 22 Nov 83                  | Proj No:                 | SWOG 8229  | Status: | Ongoing |
| TITLE: Combined Modality Therapy for Multiple Myeloma, VMCP-VBAP for Remission Induction Therapy: VMCP + Levamisole vs Sequential Half-Body Radiotherapy + Vincristine-Prednisone for Maintenance or Consolidation. Evaluation...Phase II |                            |                          |  |         |         |
| Start Date  | 10 Dec 82                  | Est Comp Date:           | Unknown  |         |         |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC  |                            |                          | Facility<br>Brooke Army Medical Center                   |         |         |
| Dept/Sec<br>Department of Medicine/Oncology   |                            |                          | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |         |         |
| Key Words:<br>Multiple myeloma  |                            |                          |  |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: |  |         |         |

Objectives: To compare the effectiveness of two intermittent pulse schedules of the chemotherapy combination of Vincristine, Melphalan, Cyclophosphamide and Prednisone (VMCP) plus Vincristine, BCNU, Adriamycin and Prednisone (VBAP) (alternating versus syncopated) for the induction of remissions in previously untreated patients with multiple myeloma.

For patients proven to achieve remission (at least 75% tumor regression after induction), to compare the value of 12 months of chemoimmunotherapy maintenance, VMCP + Levamisole, versus a consolidation program consisting of sequential half-body radiotherapy along with Vincristine and Prednisone followed by unmaintained remission.

For patients who only achieve improvement (50%-74% tumor regression) on chemotherapy induction, to determine whether sequential half-body radiotherapy along with Vincristine and Prednisone will increase the remission rate (at least 75% tumor regression).

To determine whether sequential half-body radiotherapy along with Vincristine and Prednisone can serve as an effective form of induction therapy for patients who fail to respond to chemotherapy or suffer early relapse.

Technical Approach: Only previously untreated patients with the diagnosis of multiple myeloma are eligible. This is a first-line study and only patients without prior cytotoxic chemotherapy are eligible.

Progress: Two patients have been entered on the study. It is too early to report any positive or negative responses.

Detail Summary Sheet

Date: 22 Nov 83 Proj No: SWOG 8231 Status: Ongoing  
 TITLE:

**Chemotherapy of Extragonadal Germinal Cell Neoplasms, Phase II**

|   |   |
|---|---|
| Start Date <u>8 Jul 83</u>  | Est Comp Date: <u>Unknown</u>                                   |
| Principal Investigator<br><u>J. Dean McCracken, M.D., COL, MC</u> | Facility<br><u>Brooke Army Medical Center</u>                   |
| Dept/Sec<br><u>Department of Medicine/Oncology</u>                | Associate Investigators:<br><u>James F. Boyd, M.D., LTC, MC</u> |
| Key Words:<br><u>Germinal cell neoplasm</u>                       |   |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:                                      |
|   | Periodic Review Results:  |

**Objectives:** To determine the effectiveness of alternating combination chemotherapy consisting of VBP (Vinblastine, Bleomycin and Cis-platinum) and EBAP (Bleomycin, Adriamycin, Cis-platinum and VP-16) in patients with metastatic germinal cell neoplasms arising in extragonadal sites.

To determine the overall toxicity of the alternating combination of VBP and EBAP.

To determine the role of surgical removal of residual disease following this drug combination in partially responding patients.

To compare the response rates observed in this study with those reported by other investigators.

**Technical Approach:** Patients presenting with a histologically confirmed diagnosis of non-resectable extragonadal germ cell tumors are eligible for this study. All patients should have clearly measurable disease, or an abnormally elevated beta HCG and/or alpha fetoprotein. Patients with extragonadal seminomatous and non-seminomatous neoplasms will be eligible for treatment on this study, but will be analyzed separately.

Therapy will follow the schema outlined in the study protocol.

**Progress:** One patient has been entered on this study. It is too early to report any definitive response to therapy.

# Detail Summary Sheet

|  |                            |                              |           |         |         |
|--|----------------------------|------------------------------|-----------|---------|---------|
| Date:  | 22 Nov 83                  | Proj No:                     | SWOG 8232 | Status: | Ongoing |
| TITLE: Treatment of Limited Small Cell Lung Cancer with VP16-/Cis-Platinum, Alternating with Vincristine/Adriamycin/Cyclophosphamide and Radiation Therapy vs Concurrent VP-16/Vincristine/Adriamycin...Radiation Therapy, Phase III |                            |                              |           |         |         |
| Start Date   | 14 Jan 83                  | Est Comp Date:               | Unknown   |         |         |
| Principal Investigator   |                            | Facility                     |           |         |         |
| J. Dean McCracken, M.D., COL, MC   |                            | Brooke Army Medical Center   |           |         |         |
| Dept/Sec   |                            | Associate Investigators:     |           |         |         |
| Department of Medicine/Oncology  |                            | James F. Boyd, M.D., LTC, MC |           |         |         |
| Key Words:   |                            |                              |           |         |         |
| Limited small cell lung cancer   |                            |                              |           |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results:     |           |         |         |

Objectives: To compare the efficacy of alternating non-cross-resistant, multidrug regimens with concurrent combination chemotherapy as remission induction in patients with limited small cell lung carcinoma.

To determine the toxicity of these treatment programs.

Technical Approach: All patients must have histologically proven small cell carcinoma of the lung. Prior to treatment, patients should be staged as to the extent of disease. Only patients with limited disease are eligible for this study. They must have evaluable or measurable disease. Patients having a prior surgical procedure are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients from BAMC have been enrolled.



# Detail Summary Sheet

|   |                                  |                          |                          |                              |         |
|---|----------------------------------|--------------------------|--------------------------|------------------------------|---------|
| Date:   | 22 Nov 83                        | Proj No:                 | SWOG 8237                | Status:                      | Ongoing |
| TITLE:  |                                  |                          |                          |                              |         |
| Evaluation of Continuous Infusion Vinblastine Sulfate in Pancreatic Adenocarcinoma, Phase II  |                                  |                          |                          |                              |         |
| Start Date  | 8 Jul 83                         | Est Comp Date:           | Unknown                  |                              |         |
| Principal Investigator  | J. Dean McCracken, M.D., COL, MC |                          | Facility                 | Brooke Army Medical Center   |         |
| Dept/Sec  | Department of Medicine/Oncology  |                          | Associate Investigators: | James F. Boyd, M.D., LTC, MC |         |
| Key Words:  | Pancreatic adenocarcinoma        |                          |                          |                              |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:       | Periodic Review Results: |                          |                              |         |
| Objective: To determine the clinical response rate of a five-day continuous infusion of vinblastine sulfate in pancreatic adenocarcinoma. |                                  |                          |                          |                              |         |

Technical Approach: To be eligible, patients must have a pathologically verified diagnosis of pancreatic adenocarcinoma. They must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks. Patients must have recovered from the toxicities of previous chemotherapy and/or radiotherapy and have demonstrated progressive disease.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered on this study. It is too early to report any positive or negative response.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: SWOG 8239 Status: Ongoing

## TITLE:

Evaluation of Spirogermanium in CNS Tumors, Phase II.

|                            |                                  |                          |                              |
|----------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date                 | 8 Apr 83                         | Est Comp Date:           | Unknown                      |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec                   | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | CNS tumors                       |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:       | Periodic Review Results: |                              |

Objectives: To determine the antitumor activity of Spirogermanium in malignant gliomas by evaluation of response-rate.

To determine the qualitative and quantitative toxicities of Spirogermanium given in a Phase II setting.

To estimate the duration of survival experienced by these patients.

Technical Approach: Patients must have a histologically-confirmed diagnosis of astrocytomas, Grades III and IV; ependyoblastoma; medulloblastoma; or anaplastic oligodendroglioma. They must have failed primary surgical and/or radiation therapies and not be eligible for high higher priority protocols. All should have received adequate prior radiotherapy. All patients must have a measurable lesion by scan and a life expectancy of six weeks or more.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered on this study. It is too early to report any positive or negative response to therapy.

# Detail Summary Sheet

|   |                                  |                          |                              |         |         |
|---|----------------------------------|--------------------------|------------------------------|---------|---------|
| Date:   | 23 Nov 83                        | Proj No:                 | SWOG 8241                    | Status: | Ongoing |
| TITLE: Treatment for Advanced Non-Small Cell Lung Cancer: PVpvs PVpM vs PVe vs PVeMi vs FOMi/CAP, Phase III |                                  |                          |                              |         |         |
| Start Date  | 11 Mar 83                        | Est Comp Date:           | Unknown                      |         |         |
| Principal Investigator  | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |         |         |
| Dept/Sec  | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |         |         |
| Key Words:  | Non-small cell lung cancer       |                          |                              |         |         |

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|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To directly compare the efficacy and toxicity of Cis-platinum plus VP-16 (PVp) versus Cis-platinum plus Vinblastine (PVe) in patients with advanced (TNM Stage III M1) non-small cell lung cancer (NSCLC). |                            |                          |

To compare the response rate, response duration, survival and toxicity of Cis-platinum plus VP-16 (PVp) to Cis-platinum plus VP16 plus MGBG (PVpM).

To compare the response rate, response duration, survival and toxicity of Cis-platinum plus Vinblastine (PVe) to Cis-platinum plus Vinblastine plus Mitomycin-C (PVeMi).

To re-evaluate and compare the activity of FOMi/CAP to PVp, PVpM, PVe and PVeMi using a fiver-arm, randomized study design.

To evaluate differences in response rates amont patients with squamous cell carcinoma, adenocarcinoma or large cell undifferentiated carcinoma of the lung.

Technical Approach: All patients with a histologically or cytologically confirmed diagnosis of squamous cell carcinoma, adenocarcinoma or large cell carcinoma of the lung are eligible for this study. The patient's clinical presentation should be compatible with a neoplasm of bronchogenic origin.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been enrolled on this study. It is too early to report any meaningful results.

# Detail Summary Sheet

Date: 23 Nov 83 Proj No: SWOG 8244 Status: Ongoing

## TITLE:

Clinical Antitumor Activity of Vinblastine Sulfate in Diffuse Mesothelioma, Phase II

Start Date 10 Jun 83 Est Comp Date: Unknown

Principal Investigator J. Dean McCracken, M.D., COL, MC Facility Brooke Army Medical Center

Dept/Sec Department of Medicine/Oncology Associate Investigators: James F. Boyd, M.D., LTC, MC

Key Words: Mesothelioma

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine the clinical response rate of five-day continuous infusion vinblastine sulfate in diffuse malignant mesothelioma.

Technical Approach: To be eligible, patients must hve a pathologically verified diagnosis of mesothelioma. The mesothelioma may arise either in the thorax or abdomen, but must be of the diffuse malignant type (i.e., not locally resectable by surgery). Patients must have objectively measurable or evaluable lesion(s) excluding CNS metastases and a life expectancy of at least eight weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients from BAMC have been enrolled on this protocol.

# Detail Summary Sheet

Date: 23 Nov 83 Proj No: SWOG 8245 Status: Ongoing  
TITLE:

Combination Chemotherapy of Unfavorable Histology Non-Hodgkin's Lymphoma with CHOP and CVB (Alternating), Phase II

|  |  |
|--|--|
| Start Date 11 Mar 83                                       | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Non-Hodgkin's Lymphoma                       |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To gain experience with a treatment program utilizing a combination of two alternating non-cross resistant drug regimens in the treatment of "poor prognosis" lymphomas.

To determine an approximate complete remission rate to the Cyclophosphamide, Adriamycin, Vincristine, and Prednisone (CHOP)/Cis-platinum, Vinblastine, and Bleomycin (CVB) treatment program prior to initiating a group-wide phase III study utilizing this program.

Technical Approach: Biopsy proven previously untreated patients with Stage II-IV non-Hodgkin's lymphoma, "poor prognosis" histology (diffuse poorly differentiated lymphocytic lymphoma, diffuse histiocytic lymphoma, nodular histiocytic lymphoma, diffuse mixed lymphoma, undifferentiated lymphoma, lymphoblastic lymphoma, and immunoblastic sarcoma) will be eligible for treatment with this regimen.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered on this study. It is too early to report any meaningful results of therapy.

# Detail Summary Sheet

Date: 23 Nov 83 Proj No: SWOG 8263 Status: Ongoing

## TITLE:

Combined Radiation Therapy and Chemotherapy as Adjuvant Treatment for Duke's B2-C Colon Cancer, Phase I-II, Pilot

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 8 Jul 83                         | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Duke's B2-C colon cancer         |                          |                              |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the immediate and delayed toxicity of two adjuvant therapy programs for patients with Dukes B2-C colon cancer: intravenous bolus 5-fluorouracil and whole abdominal radiation therapy begun simultaneously four to six weeks postoperatively.

Technical Approach: Patients must have a histologically confirmed diagnosis of Duke's C1 (limited to the serosa with positive nodes) or C2 (extension through the serosa with positive nodes). Patients entering the study postoperatively must have an adequate surgical procedure of the tumors of the cecum and ascending colon, proximal transverse colon, splenic flexure or descending colon, or sigmoid. They must not have had any prior malignancies, inflammatory bowel disease or liver disease. Patients may not have received prior radiation therapy or chemotherapy.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered on this study. It is too early to report any meaningful results.

# Detail Summary Sheet

|  |                                  |                          |                               |         |         |
|--|----------------------------------|--------------------------|-------------------------------|---------|---------|
| Date:  | 23 Nov 83                        | Proj No:                 | SWOG 8264                     | Status: | Ongoing |
| TITLE: Combination Chemotherapy with m-AMSA, Cis-Platinum and MGBG for Refractory Lymphoma, Phase II |                                  |                          |                               |         |         |
| Start Date   | 8 Jul 83                         | Est Comp Date:           | Unknown                       |         |         |
| Principal Investigator   | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center    |         |         |
| Dept/Sec   | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC  |         |         |
| Key Words:   | Refractory lymphomas             |                          | Glenn M. Mills, M.D., MAJ, MC |         |         |

|   |                            |                          |
|---|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To determine if the three drug combination of methanesulfonamide N-4- (9-acridinyl-amino)-3-methoxyphenyl (m-AMSA), and methyl-glyoxal bis-guanylhydrazone (MGBG) has reasonable activity in patients with refractory unfavorable histology lymphomas; response rate and response duration will be assessed also. |                            |                          |

To determine the toxicities of this combination of drugs.

Technical Approach: Eligible patients must have histologically confirmed, unfavorable histology, non-Hodgkin's lymphomas refractory to standard chemotherapy regimens. They must have measurable disease and a life expectancy of at least eight weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients from BAMC have been entered on this protocol.

# Detail Summary Sheet

Date: 23 Nov 83 Proj No: SWOG 8269 Status: Ongoing

## TITLE:

Concurrent Chemo-Radiotherapy for Limited Small Cell Carcinoma of the Lung,  
Phase II - Pilot

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 8 Oct 82                         | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Small cell carcinoma of lung     |                          |                              |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To explore the response rate with the concurrent use of radiation therapy plus chemotherapy utilizing Cis-platinum VP-16 and Vincristine in limited small cell carcinoma of the lung.

To observe the toxicities of this combined modality program.

Technical Approach: Patients with a histologically or cytologically proven diagnosis of small cell carcinoma of the lung will be eligible for this study. All patients must have so-called "limited disease". This is defined as disease confined to one hemithorax, mediastinum, hilar and supraclavicular areas, which could be encompassed within a single radiation therapy port. Patients having had surgical diagnostic or therapeutic techniques are eligible, except if all gross evidence of disease has been removed after surgical resection.

Therapy will follow the schema outlined in the study protocol.

Progress: Five patients have been entered on this study. It is too early to report any meaningful results.



# Detail Summary Sheet

|   |                            |                              |           |         |         |
|---|----------------------------|------------------------------|-----------|---------|---------|
| Date:   | 23 Nov 83                  | Proj No:                     | SWOG 8291 | Status: | Ongoing |
| TITLE: The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study #1. A Randomized Trial of Adjuvant Doxorubicin (Adriamycin) versus Standard Therapy (A Delay of Chemotherapy Until the Time of Possible Relapse) |                            |                              |           |         |         |
| Start Date  | 11 Mar 83                  | Est Comp Date:               | Unknown   |         |         |
| Principal Investigator  |                            | Facility                     |           |         |         |
| J. Dean McCracken, M.D., COL, MC  |                            | Brooke Army Medical Center   |           |         |         |
| Dept/Sec  |                            | Associate Investigators:     |           |         |         |
| Department of Medicine/Oncology   |                            | James F. Boyd, M.D., LTC, MC |           |         |         |
| Key Words:  |                            |                              |           |         |         |
| Soft tissue sarcoma   |                            |                              |           |         |         |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results:     |           |         |         |

Objective: This prospective randomized study is designed to evaluate the efficacy of adjuvant Adriamycin compared to standard treatment (a delay of chemotherapy until the time of demonstrated relapse) in the management of patients with Stages IIB, IIIA-C and tissue sarcoma in terms of local recurrence rate, disease-free interval, and survival.

Technical Approach: For inclusion in this study, patients must have a histopathologically proven diagnosis of soft tissue sarcoma Stages IIB, IIIA-C, and IVA. The tumor may be either previously untreated or a local recurrence.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been enrolled on this protocol.

# Detail Summary Sheet

Date: 23 Nov 83 Proj No: SWOG 8292 Status: Ongoing

## TITLE:

Treatment for Brain Metastases, Phase III. Intergroup Study

|                            |                                  |                          |                              |
|----------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date                 | 8 Apr 83                         | Est Comp Date:           | Unknown                      |
| Principal Investigator     | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec                   | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:                 | Brain metastases                 |                          |                              |
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost:       | Periodic Review Results: |                              |

Objectives: To test whether the addition of surgery before radiation therapy is a significant improvement over radiation therapy alone in the treatment of patient with apparent single brain metastases. Endpoints studied will be:

One year survival rates and median survival times.

Local control rates of brain metastases one month and six months after treatment.

Improvement of neurological deficit as measured by the percentage of patients with improved neurological function.

To evaluate patient refusal with respect to the surgical component.

Technical Approach: All patients having histologically confirmed cancer with evidence of a potentially resectable single intracranial mass lesion as documented by a contrast-enhanced CAT scan are eligible. Only patients with apparently resectable cerebellar or cerebral cortex lesions will be eligible. Patients with bronchogenic carcinoma should have control of the primary tumor and no other metastases prior to admission on this study.

Progress: This is a new study. No patients from BAMC have been entered on this protocol.

Detail Summary Sheet

|   |  |                 |
|---|--|-----------------|
| Date: 23 Nov 83   | Proj No: SWOG 8294                                       | Status: Ongoing |
| TITLE: Evaluation of Adjuvant Therapy and Biological Parameters in Node Negative Operable Female Breast Cancer (ECOG EST-1180), Intergroup, Study (Observation Only) (Patients Randomized to CMFP Chemotherapy) |  |                 |
| Start Date 11 Mar 83  | Est Comp Date: Unknown                                   |                 |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC  | Facility<br>Brooke Army Medical Center                   |                 |
| Dept/Sec<br>Department of Medicine/Oncology   | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |                 |
| Key Words:<br>Breast cancer   |  |                 |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

**Objectives:** To assess the impact of short-term intensive chemotherapy with CMFP to prevent disease recurrence and prolong survival in N- patients with any size ER- tumor and N- patients with ER+ tumors whose pathological size is greater than or equal to 3 cm.

To assess the impact of surgical procedures, ER status, menopausal status and tumor size.

To develop guidelines referable to histopathological features of N- tumors which are reproducible and assess their prognostic impact for disease-free survival and survival.

To assess the value to CEA in predicting recurrence and survival rates.

To assess the natural history of a subgroup with N-, ER+ small tumors.

**Technical Approach:** All female patients having had at least a total mastectomy with an axillary dissection or total mastectomy with low axillary dissection for potentially curable breast carcinoma as defined in this protocol and having no histopathological evidence of axillary node involvement will be considered for inclusion in this study.

Therapy will follow the schema outlined in the study protocol.

**Progress:** This is a new study. No patients from BAMC have been entered on this protocol.

# Detail Summary Sheet

Date: 23 Nov 83 Proj No: SWOG 8303 Status: Ongoing

TITLE:

Evaluation of 2'Deoxycoformycin in Refractory Multiple Myeloma, Phase II

|  |   |
|--|---|
| Start Date 8 Jul 83  | Est Comp Date: Unknown  |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center  |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC<br>Glenn M. Mills, M.D., MAJ, MC |
| Key Words:<br>Multiple myeloma                             |   |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the response rate and response duration of refractory multiple myeloma treated with low dose 2'Deoxycoformycin used in a single dose, every two week schedule.

To define the qualitative and quantitative toxicities of 2'Deoxycoformycin administered in a Phase II study.

Technical Approach: 2'Deoxycoformycin is intended for therapy of patients with multiple myeloma who have had prior exposure to and progression of disease on protocols of higher priority. All patients must have a pathologically verified histologic diagnosis of multiple myeloma. Only symptomatic patients or those with demonstrated progressive disease are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This is a new study. No patients have been entered.

# Detail Summary Sheet

Date: 23 Nov 83 Proj No: SWOG 8304 Status: Ongoing

## TITLE:

Evaluation of L-Alanosine in Metastatic Carcinoma of the Breast

|  |  |
|--|--|
| Start Date 8 Jul 83  | Est Comp Date: Unknown                                   |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC | Facility<br>Brooke Army Medical Center                   |
| Dept/Sec<br>Department of Medicine/Oncology                | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |
| Key Words:<br>Metastatic carcinoma of breast               |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the antitumor activity as determined by response rate and duration of response of L-Alanosine used on a three day, every three week schedule in patients with metastatic carcinoma of the breast who have failed on standard therapy.

To determine the nature and degree of toxicity of L-Alanosine.

Technical Approach: All patients with metastatic carcinoma of the breast resistant to standard chemotherapeutic agents are eligible. Patients must have measurable or evaluable disease and a life expectancy of at least nine weeks.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient from BAMC has been entered on this study. It is too early to report any meaningful results.

# Detail Summary Sheet

Date: 23 Nov 83 Proj No: SWOG 8305 Status: Ongoing

## TITLE:

Chemotherapy of Metastatic Colorectal Carcinoma with 5-FU and Folinic Acid, Phase II

|                        |                                  |                          |                              |
|------------------------|----------------------------------|--------------------------|------------------------------|
| Start Date             | 8 Jul 83                         | Est Comp Date:           | Unknown                      |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                 | Brooke Army Medical Center   |
| Dept/Sec               | Department of Medicine/Oncology  | Associate Investigators: | James F. Boyd, M.D., LTC, MC |
| Key Words:             | Colorectal carcinoma             |                          |                              |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the toxicity of 5-fluorouracil (5-FU) and folinic acid (CF) therapy in patients with metastatic colorectal carcinoma.

To determine the response-rate in previously untreated patients receiving 5-FU and folinic acid.

Technical Approach: Patients must have clinically measurable disease to qualify for this study. They must have biopsy-proven adenocarcinoma arising from the colon or rectum. Obstructive lesions in the colon and rectum must have been bypassed or adequately maintained by decompression measures.

Therapy will follow the schema outlined in the study protocol.

Progress: Five patients have been entered on this study. It is too early to report any meaningful results.

# Detail Summary Sheet

|   |  |                 |
|---|--|-----------------|
| Date: 23 Nov 83   | Proj No: SWOG 8311                                       | Status: Ongoing |
| TITLE: Combination Chemotherapy with Cis-Platinum, Vinblastine, and Methylglyoxal Bis (Guanylhydrazone) (MGBG) in Epidermoid Carcinoma of the Esophagus |  |                 |
| Start Date 9 Sep 83   | Est Comp Date: Unknown                                   |                 |
| Principal Investigator<br>J. Dean McCracken, M.D., COL, MC  | Facility<br>Brooke Army Medical Center                   |                 |
| Dept/Sec<br>Department of Medicine/Oncology   | Associate Investigators:<br>James F. Boyd, M.D., LTC, MC |                 |
| Key Words:<br>Epidermoid carcinoma  |  |                 |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To define the response rate and duration, as well as survival duration, in patients with advanced epidermoid carcinoma of the esophagus when treated with Cis-platinum, Vinblastine and MGBG.

To determine the toxicity of this regimen in the treatment of epidermoid carcinoma of the esophagus.

Technical Approach: All patients must have measurable disease and must have histologically or cytologically confirmed diagnosis of epidermoid carcinoma of the esophagus.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered on this study. It is too early to report any meaningful results.

# Detail Summary Sheet

|   |                              |                          |
|---|------------------------------|--------------------------|
| Date: 23 Nov 83   | Proj No: SWOG 8360           | Status: Ongoing          |
| TITLE: Use of the Surgically Implanted "Infusaid" Pump for Ambulatory Outpatient Hepatic Arterial Chemotherapy for Patients with Colon Cancer Metastatic to the Liver, Phase II - Pilot |                              |                          |
| Start Date 13 May 83  | Est Comp Date: Unknown       |                          |
| Principal Investigator  | Facility                     |                          |
| J. Dean McCracken, M.D., COL, MC  | Brooke Army Medical Center   |                          |
| Dept/Sec  | Associate Investigators:     |                          |
| Department of Medicine/Oncology   | James F. Boyd, M.D., LTC, MC |                          |
| Key Words:  |                              |                          |
| Infusaid pump   |                              |                          |
| Colon cancer  |                              |                          |
| Hepatic arterial chemotherapy   |                              |                          |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:   | Periodic Review Results: |

Objectives: To determine the response rate, disease-free interval and survival in patients with colon carcinoma metastatic to the liver treated using the "Infusaid" pump with continuous intrahepatic arterial infusions of 5-FUDR and monthly cis-platinum injections via the side port.

To determine the feasibility of utilizing the "Infusaid" pump to deliver intraarterial chemotherapy in a cooperative group setting.

Technical Approach: To be eligible for inclusion on this study, patients must have a biopsy-proven colorectal cancer metastatic to the liver as the primary factor determining their survival and quality of life. Patients will be stratified for hepatic-only versus extra-hepatic disease at the time of registration. Patients must have an estimated survival of greater than 60 days.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered on this study. It is too early to report any meaningful results.



# Detail Summary Sheet

Date: **23 Nov 83** Proj No: **SWOG 8391** Status: **Ongoing**

TITLE:

**The Intergroup Adult Adjuvant Soft Tissue Sarcoma Study Protocol #2: A Randomized Trial of Adjuvant Doxorubicin (Adriamycin) vs Standard Therapy**

Start Date **10 Jun 83** Est Comp Date: **Unknown**

Principal Investigator Facility

**J. Dean McCracken, M.D., COL, MC** **Brooke Army Medical Center**

Dept/Sec Associate Investigators:

**Department of Medicine/Oncology** **James F. Boyd, M.D., LTC, MC**

Key Words:

**Soft tissue sarcoma**

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

**Objectives:** To evaluate the effectiveness of adjuvant chemotherapy in improving the local control rate in inoperable, unresectable or incompletely resected soft tissue sarcomas treated with radiotherapy.

To determine the effect of adjuvant chemotherapy on the incidence of metastases, disease-free interval and survival.

To evaluate tolerance (with emphasis on local tissue tolerance in the irradiated area) to combined chemotherapy and radiation therapy.

**Technical Approach:** Eligible patients must have histopathologically proven diagnosis of soft tissue sarcoma. Patients with localized sarcomas, newly diagnosed or recurrent after previous surgery who are not candidates for curative surgical resection, or who have residual tumor following an incomplete surgical resection will be candidates for the study.

Therapy will follow the schema outlined in the study protocol.

**Progress:** This is a new study. No patients have been entered.

# Detail Summary Sheet

Date: 18 Nov 82 Proj No: Status: Terminated

## TITLE:

Aclacinomycin - Phase II Evaluation in Lung Cancer - Pilot Study

|                        |                                  |                            |
|------------------------|----------------------------------|----------------------------|
| Start Date             | 9 Apr 82                         | Est Comp Date:             |
| Principal Investigator | J. Dean McCracken, M.D., COL, MC | Facility                   |
| Dept/Sec               | Department of Medicine/Oncology  | Brooke Army Medical Center |
| Key Words:             | Lung cancer                      | Associate Investigators:   |
|                        | Aclacinomycin                    |                            |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objective: To evaluate the activity of aclacinomycin against carcinoma of the lung in minimally pretreated patients. |                            |                          |

Technical Approach: Patients must have histologically proven advanced lung cancer. Patients who have previously received more than one prior chemotherapeutic regimen will be eligible only with approval of the principal investigator. Preferably, patients with non oat cell lung cancer or extensive small cell cancer will have received no prior therapy. Patients with small cell cancer failing first line SWOG protocols are eligible.

Progress: No patients were entered on this study. The study was terminated due to release from active duty of MAJ John D. Cowan.

# Detail Summary Sheet

Date: 16 Nov 82 Proj No: GOG 20 Status: Ongoing  
 TITLE: A Randomized Comparison of Adriamycin vs No Further Therapy in  
 Patients with Uterine Sarcomas, Stage I and II, Phase III

|   |                            |                |         |
|---|----------------------------|----------------|---------|
| Start Date                              | FY 81                      | Est Comp Date: | Unknown |
| Principal Investigator                  | Facility                   |                |         |
| Charles Capen, M.D., LTC, MC            | Brooke Army Medical Center |                |         |
| Dept/Sec                                | Associate Investigators:   |                |         |
| Department of Obstetrics and Gynecology |                            |                |         |
| Key Words:                              |                            |                |         |
| Uterine Sarcoma                         |                            |                |         |
| Adriamycin                              |                            |                |         |

|  |                  |                          |
|--|------------------|--------------------------|
| Accumulative MEDCASE   | Est Accumulative | Periodic                 |
| Cost:  | OMA Cost:        | Review Results: Continue |
| Objective: To determine if adjuvant chemotherapy will improve the cure rate in uterine sarcomas, Stage I and II. |                  |                          |

Technical Approach: Patients with histologically proven sarcomas of the uterine corpus will be considered if they have Stage I or Stage II disease clinically, and if they have no known gross residual disease following surgery. Preoperative or postoperative pelvic radiotherapy may be given at the discretion of the principal investigator, but a decision about this mode of therapy must be made prior to the chemotherapy randomization.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients remain on this study. Groupwide, there has been no significant difference between survival and progression-free interval. Moreover, Mantel-Haentzel techniques adjusting for such parameters as stage, histology, prior radiotherapy and various combinations of these three have been employed, revealing no treatment difference.

# Detail Summary Sheet

|   |           |                |                            |         |         |
|---|-----------|----------------|----------------------------|---------|---------|
| Date:   | 16 Nov 83 | Proj No:       | GOG-24                     | Status: | Ongoing |
| TITLE: Treatment of Women with Cervical Cancer Stage IIB, IIIB, IVA, Confined to the Pelvis and/or para-aortic nodes with Radiotherapy Alone vs Radiotherapy plus Immunotherapy (Phase II). |           |                |                            |         |         |
| Start Date  | FY 78     | Est Comp Date: |                            | Unknown |         |
| Principal Investigator  |           |                | Facility                   |         |         |
| Charles Capen, M.D., LTC, MC  |           |                | Brooke Army Medical Center |         |         |
| Dept/Sec  |           |                | Associate Investigators:   |         |         |
| Department of Obstetrics and Gynecology   |           |                |                            |         |         |
| Key Words:  |           |                |                            |         |         |
| Cervical cancer   |           |                |                            |         |         |
| Radiotherapy  |           |                |                            |         |         |
| Immunotherapy   |           |                |                            |         |         |

|   |                  |                          |
|---|------------------|--------------------------|
| Accumulative MEDCASE  | Est Accumulative | Periodic                 |
| Cost:   | OMA Cost:        | Review Results: Continue |
| Objective: To assess the therapeutic effectiveness of immunotherapy (intravenous C-parvum) used concomitantly with radiation in patients with advanced carcinoma of the uterine cervix. |                  |                          |

Technical approach: Patients with histologically confirmed, previously untreated carcinoma of the uterine cervix (adenocarcinoma or squamous carcinoma) are eligible.

Therapy will be in accordance with the schema outlined in the study protocol.

Progress: No patients have been entered on the study.

# Detail Summary Sheet

|  |  |                                   |
|--|--|-----------------------------------|
| Date: 16 Nov 83  | Proj No: GOG-25                        | Status: Ongoing                   |
| TITLE: A Randomized Comparison of Melphalan Therapy Alone vs Melphalan plus Immunotherapy (C. Parvum) in the Treatment of Women with Stage III (Optimal) Epithelial Carcinoma of the Ovary (Phase II). |  |                                   |
| Start Date FY 78   | Est Comp Date: Unknown                 |                                   |
| Principal Investigator<br>Charles Capen, M.D., LTC, MC   | Facility<br>Brooke Army Medical Center |                                   |
| Dept/Sec<br>Department of Obstetrics and Gynecology  | Associate Investigators:               |                                   |
| Key Words:<br>Epithelial carcinoma, ovary<br>Immunotherapy<br>C. Parvum  |  |                                   |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost:             | Periodic Review Results: Continue |
| Objective: To determine the efficacy of adjuvant nonspecific immunotherapy to standard alkylating agent therapy in patients with Stage III optimal carcinoma of the ovary.                             |  |                                   |

Technical Approach: Patients in "optimal" category (3 cm or less greatest diameter of residual tumor(s) with proven primary Stage III epithelial cancer of the ovary) who have undergone tumor-reductive surgery will be included in the study.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient remains on the study and continues to respond to therapy.

# Detail Summary Sheet

Date: 16 Nov 83      Proj No: GOG-26      Status: Ongoing

## TITLE:

Master Protocol for Phase II Drug Studies in Treatment of Advanced, Recurrent Pelvic Malignancies.

|   |                             |
|---|-----------------------------|
| Start Date      FY 78                   | Est Comp Date:      Unknown |
| Principal Investigator                  | Facility                    |
| Charles Capen, M.D., LTC, MC            | Brooke Army Medical Center  |
| Dept/Sec                                | Associate Investigators:    |
| Department of Obstetrics and Gynecology |                             |

## Key Words:

Pelvic malignancies  
Chemotherapy

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: This protocol constitutes a Phase II design outlining the procedures that will be performed to screen for activity of new agents or drug combinations in patients with advanced recurrent pelvic malignancies. Its intent is to determine the efficacy of chemotherapeutic agents in patients whose advanced malignancies have been resistant to high priority methods of treatment.

Technical Approach: This is a study of multiple chemotherapeutic agents. Therapy will follow the schema outlined in the study protocol. Agents to be used in this study include: Piperazinedione, Cis-platinum, VP-16, Galacticol, Baker's Antifol, ICRF-159, Maytansine, m-AMSA and Yoshi 864.

Progress: No patients have been registered on this study. However, the study is kept open in the event the need should arise for entering a patient on this protocol.

# Detail Summary Sheet

|  |                            |                                   |
|--|----------------------------|-----------------------------------|
| Date: 16 Nov 83  | Proj No: GOG 34            | Status: Ongoing                   |
| TITLE: A Randomized Study of Adriamycin as an Adjuvant After Surgery and Radiation Therapy in Patients with High Risk Endometrial Carcinoma, Stage I, and Occult Stage II. |                            |                                   |
| Start Date FY 78   | Est Comp Date: Unknown     |                                   |
| Principal Investigator   | Facility                   |                                   |
| Charles Capen, M.D., LTC, MC   | Brooke Army Medical Center |                                   |
| Dept/Sec   | Associate Investigators:   |                                   |
| Department of Obstetrics and Gynecology  |                            |                                   |
| Key Words:   |                            |                                   |
| Endometrial carcinoma  |                            |                                   |
| Radiation therapy  |                            |                                   |
| Adriamycin   |                            |                                   |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
| Objective: To study differences in morbidity and patient survival as functions of various tumor growth patterns as well as treatments.                                     |                            |                                   |

Technical Approach: All patients with primary, previously untreated, histologically confirmed invasive carcinoma of the endometrium Stage I, and Stage II occult, all grades, with one or more of the following high risk criteria are eligible: (1) all lesions with equal to or greater than one-half myometrial involvement; (2) positive pelvic and/or para-aortic nodes; (3) microscopic evidence of cervical involvement but no gross clinical involvement of the cervix. The following types of histologically confirmed uterine carcinoma are eligible: adenocarcinoma, adenoacanthoma, adenosquamous carcinoma.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients remain on the study. It is too early to draw any meaningful conclusions.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: GOG 36 Status: Ongoing

## TITLE:

Surgical-Pathologic Study of Women with Squamous Cell Carcinoma of the Vulva.

|   |                            |
|---|----------------------------|
| Start Date FY 78                        | Est Comp Date: Unknown     |
| Principal Investigator                  | Facility                   |
| Charles Capen, M.D., LTC, MC            | Brooke Army Medical Center |
| Dept/Sec                                | Associate Investigators:   |
| Department of Obstetrics and Gynecology |                            |
| Key Words:                              |                            |
| Squamous cell carcinoma of vulva        |                            |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To determine the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor in millimeters, histologic grade, and site and number of positive lymph nodes in Stage I-IV carcinoma of the vulva.

To rapidly accumulate prospectively significant surgical pathologic data for development of further protocols for subsets of disease identified.

To determine morbidity of primary radical surgical therapy.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive squamous cell carcinoma of the vulva clinically determined to be Stage I through IV are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study. Groupwide, it is too early to draw any meaningful conclusions from available data.



# Detail Summary Sheet

|   |  |                                   |
|---|--|-----------------------------------|
| Date: 16 Nov 83   | Proj No: GOG 37                        | Status: Ongoing                   |
| TITLE: Randomized Study of Radiation Therapy vs Pelvic Node Resection for Patients with Invasive Squamous Cell Carcinoma of the Vulva Having Positive Groin Nodes.  |  |                                   |
| Start Date FY 78  | Est Comp Date: Unknown                 |                                   |
| Principal Investigator<br>Charles Capen, M.D., LTC, MC  | Facility<br>Brooke Army Medical Center |                                   |
| Dept/Sec<br>Department of Obstetrics and Gynecology   | Associate Investigators:               |                                   |
| Key Words:<br>Squamous cell carcinoma of vulva  |  |                                   |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:             | Periodic Review Results: Continue |
| Objective: To determine the benefit and morbidity of adding adjunctive radiation therapy to pelvis and groin for patients with positive groin nodes at radical vulvectomy and bilateral groin dissection. |  |                                   |

Technical Approach: All patients with primary, previously untreated, histologically confirmed squamous cell carcinoma of the vulva such that radical vulvectomy suffices to remove all of the local lesion and whose surgery revealed that there were nodes in the groin on one or both sides containing metastatic carcinoma are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study. Groupwide, no reportable data are available at this time.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: GOG 40 Status: Ongoing

## TITLE:

A Clinical-Pathologic Study of Stage I and II Uterine Sarcomas.

|                        |   |                          |                            |
|------------------------|---|--------------------------|----------------------------|
| Start Date             | FY 79                                   | Est Comp Date:           | Unknown                    |
| Principal Investigator | Charles Capen, M.D., LTC, MC            | Facility                 | Brooke Army Medical Center |
| Dept/Sec               | Department of Obstetrics and Gynecology | Associate Investigators: |                            |
| Key Words:             | Uterine sarcoma                         |                          |                            |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objective: To determine the incidence of pelvic and aortic lymph node metastases associated with Stage I and II uterine sarcomas, the relationship of these node metastases to other important prognostic factors such as mitotic index of the tumor, and the complication rate of the procedures.

Technical Approach: All patients with histologically proven uterine sarcoma clinical Stage I and II who are medically suitable for hysterectomy and lymphadenectomy are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study. Groupwide, it is too early to draw any conclusions.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: GOG 41 Status: Ongoing

TITLE:  
Surgical Staging of Ovarian Carcinoma.

|   |       |                            |         |
|---|-------|----------------------------|---------|
| Start Date                              | FY 79 | Est Comp Date:             | Unknown |
| Principal Investigator                  |       | Facility                   |         |
| Charles Capen, M.D., LTC, MC            |       | Brooke Army Medical Center |         |
| Dept/Sec                                |       | Associate Investigators:   |         |
| Department of Obstetrics and Gynecology |       |                            |         |
| Key Words:                              |       |                            |         |
| Ovarian carcinoma                       |       |                            |         |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objectives: To determine the spread of ovarian carcinoma in intraperitoneal structures and retroperitoneal lymph nodes by direct examination, cytologic sampling, and biopsy.

To establish a surgical protocol for patients entered into GOG ovarian cancer treatment protocols.

To determine the complication rate of the procedures.

Technical Approach: Patients with all histologic types of primary ovarian cancer are eligible, including epithelial tumors, germ cell tumors, stromal tumors, and all others. Patients must be entered within two weeks of the last surgery.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered on this study. Groupwide it is too early to report any conclusions.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: GOG 42 Status: Ongoing

## TITLE:

Treatment of Recurrent or Advanced Uterine Sarcoma. A Randomized Comparison of Adriamycin vs Adriamycin and Cyclophosphamide, Phase III.

Start Date FY 79

Est Comp Date: Unknown

Principal Investigator

Facility

Charles Capen, M.D., LTC, MC

Brooke Army Medical Center

Dept/Sec

Associate Investigators:

Department of Obstetrics and Gynecology

Key Words:

Uterine sarcoma

Accumulative MEDCASE  
Cost:

Est Accumulative  
OMA Cost:

Periodic  
Review Results: Continue

Objectives: To determine if Adriamycin alone is more effective than Adriamycin and Cyclophosphamide in producing responses in advanced or recurrent uterine sarcoma.

To determine the duration of response for each different treatment arm.

Technical Approach: Patients with primary Stage III, primary Stage IV or recurrent uterine sarcoma are eligible. Both patients with measurable and non-measurable disease are eligible, but they will be analyzed separately. Patients with all cell types of uterine sarcoma are eligible.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on the study. Groupwide, the regimens are well tolerated.

# Detail Summary Sheet

|  |                            |                 |
|--|----------------------------|-----------------|
| Date: 16 Nov 83  | Proj No: GOG 43            | Status: Ongoing |
| TITLE: A Randomized Comparison of Cis-platinum 50mg/m2 IV Every 3 weeks vs Cis-platinum 100mg/m2 IV Every 3 weeks vs Cis-platinum 20mg/m2 IV Daily x 5 Days in Treatment of Patients with Advanced Carcinoma of the Cervix, Phase III. |                            |                 |
| Start Date: FY 79  | Est Comp Date: Unknown     |                 |
| Principal Investigator   | Facility                   |                 |
| Charles Capen, M.D., LTC, MC   | Brooke Army Medical Center |                 |
| Dept/Sec   | Associate Investigators:   |                 |
| Department of Obstetrics and Gynecology  |                            |                 |
| Key Words:   |                            |                 |
| Carcinoma of cervix  |                            |                 |

|  |                  |                          |
|--|------------------|--------------------------|
| Accumulative MEDCASE   | Est Accumulative | Periodic                 |
| Cost:  | OMA Cost:        | Review Results: Continue |
| Objectives: To confirm the effectiveness of cis-diamminedichloroplatinum (DDP) in advanced and recurrent squamous cell carcinoma of the cervix no longer responding to radiation therapy or surgery. |                  |                          |

To compare the frequency and duration of response and adverse effects of DDP therapy using three different doses and treatment schedules.

To evaluate the roles of serial determination of serum carcinoembryonic antigen (CEA) levels in determining extent of disease, response to treatment, and in predicting treatment failure.

Technical Approach: Eligible patients must have histologically confirmed, locally advanced, recurrent, persistent, or metastatic squamous cell carcinoma of the cervix which is resistant to curative treatment with surgery or radiotherapy. All patients must have lesions which are measurable or evaluable by physical examination. Patients will have recovered from effects of recent surgery or radiotherapy, and will be free of clinically significant infection.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: One patient has been registered on this protocol. Groupwide evaluations have shown that there is no difference in the efficacy of the three regimens; however, there is less toxicity with the lower dose.

# Detail Summary Sheet

|   |                            |                 |
|---|----------------------------|-----------------|
| Date: 16 Nov 83   | Proj No: GOG 44            | Status: Ongoing |
| TITLE: Evaluation of Adjuvant Vincristine, Dactinomycin, and Cyclophosphamide Therapy in Malignant Germ Cell Tumors of the Ovary After Resection of All Gross Tumor, Phase III. |                            |                 |
| Start Date FY 79  | Est Comp Date: Unknown     |                 |
| Principal Investigator  | Facility                   |                 |
| Charles Capen, M.D., LTC, MC  | Brooke Army Medical Center |                 |
| Dept/Sec  | Associate Investigators:   |                 |
| Department of Obstetrics and Gynecology   |                            |                 |
| Key Words:  |                            |                 |
| Germ cell tumor of ovary  |                            |                 |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To evaluate the effect of combined prophylactic vincristine, dactinomycin, and cyclophosphamide chemotherapy in patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (Grades 2 and 3), choriocarcinoma, and malignant mixed germ cell tumors of the ovary, Stages I and II after total removal of all gross tumor.

To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gonadotropin (beta HCG), when these are present, in predicting response and relapse.

To determine the role of restaging laparotomy in determining response, predicting relapse and planning further therapy.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary, Stages I or II, if previously untreated and completely resected, excluding patients with pure dysgerminoma unless classified as anaplastic, are eligible. Patients with grade 2 or 3 immature teratoma are also eligible. Patients with early Stage III disease will be accepted if all gross tumor is resected.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this protocol. As far as GOG results are concerned, it is too early to report any meaningful results.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: GOG 45 Status: Ongoing

## TITLE:

Evaluation of Vinblastine, Bleomycin, and Cis-platinum in Stage III and IV and Recurrent Malignant Germ Cell Tumors of the Ovary, Phase III.

Start Date FY 79 Est Comp Date: Unknown

Principal Investigator Facility

Charles Capen, M.D., LTC, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Obstetrics and Gynecology

## Key Words:

Malignant germ cell tumor of ovary

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To evaluate the effect of four cycles of combined Vinblastine, Bleomycin and Cis-platinum (VBP) chemotherapy in the management of patients with endodermal sinus tumor, embryonal carcinoma, immature teratoma (all grades), choriocarcinoma, and malignant germ cell tumors of the ovary with advanced or recurrent disease, incompletely resected.

To evaluate the role of serum markers, especially alpha-fetoprotein (AFP) and human chorionic gondaotropin (beta JCG), when these are present, in predicting response and relapse.

To determine the role of restaging laparotomy in patients in clinical remission, in assessing completeness of response, and in planning further therapy.

To evaluate and compare the effect of Vincristine, Dactinomycin and Cyclophosphamide (VAC) chemotherapy in patients found to have persistent disease at the time of restaging laparotomy.

To determine the need for maintenance Vinblastine therapy in patients found free of disease at restaging laparotomy.

Technical Approach: Patients with histologically confirmed malignant germ cell tumors of the ovary with advanced (Stage III-IV) or recurrent disease, incompletely resected, excluding patients with pure dysgerminoma (mature or anaplastic) are eligible. Patients with incompletely resected Stage II disease and patients previously treated with Vincristine, Dactinomycin and Cyclophosphamide are also eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study. Groupwide, there continues to be considerable toxicity; however, early results are encouraging.

# Detail Summary Sheet

|  |                            |                 |
|--|----------------------------|-----------------|
| Date: 16 Nov 83  | Proj No: GOG 46            | Status: Ongoing |
| TITLE: A Randomized Comparison of Melphalan vs Intraperitoneal Chromic Phosphate in the Treatment of Women with Stage I (exclusive of Stage IA(i) G1 and IB(i) G1) Epithelial Carcinoma of the Ovary, Phase III. |                            |                 |
| Start Date FY 79   | Est Comp Date: Unknown     |                 |
| Principal Investigator   | Facility                   |                 |
| Charles Capen, M.D., LTC, MC   | Brooke Army Medical Center |                 |
| Dept/Sec   | Associate Investigators:   |                 |
| Department of Obstetrics and Gynecology  |                            |                 |
| Key Words:   |                            |                 |
| Epithelial carcinoma of ovary  |                            |                 |

|   |                            |                                   |
|---|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
| Objective: To evaluate the relative effectiveness of Melphalan vs intraperitoneal Chromic Phosphate as adjuvant therapy in Stage I exclusive of Stage IA (i) G1 and Stage IB(i) G1 epithelial cancers of the ovary in a randomized prospective study. |                            |                                   |

Technical Approach: Patients with surgical Stage IA(i) Gs, G3; IA(ii); IB(i) G2, G3; IB(ii), and IC epithelial cancer of the ovary who have undergone optimal staging described in GOG 41 are eligible.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: One patient has been registered on this study. Groupwide, it is too early to draw any conclusions.



# Detail Summary Sheet

|   |                            |                 |
|---|----------------------------|-----------------|
| Date: 16 Nov 83   | Proj No: GOG 47            | Status: Ongoing |
| TITLE: A Randomized Study of Adriamycin + Cyclophosphamide vs Adriamycin + Cyclophosphamide + Cis-platinum in Patients with Advanced Ovarian Adenocarcinoma - Suboptimal Stage II, Stage IV and Recurrent, Phase III. |                            |                 |
| Start Date FY 80  | Est Comp Date: Unknown     |                 |
| Principal Investigator  | Facility                   |                 |
| Charles Capen, M.D., LTC, MC  | Brooke Army Medical Center |                 |
| Dept/Sec  | Associate Investigators:   |                 |
| Department of Obstetrics and Gynecology   |                            |                 |
| Key Words:  |                            |                 |
| Ovarian adenocarcinoma  |                            |                 |

|  |                            |                                   |
|--|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
| Objectives: To determine if the addition of Cis-platinum to Adriamycin plus Cyclophosphamide improves remission rate, remission duration or survival in Stage IV, suboptimal Stage III and recurrent ovarian adenocarcinoma. |                            |                                   |

To determine the frequency and duration of true complete remission using these regimens as judged at second-look laparotomy.

Technical Approach: Patients who have been diagnosed as Stage IV and suboptimal Stage III primary cases together with all recurrent cases are eligible. Both patients with measurable disease and patients without measurable disease, as a separate category, will be evaluated.

Therapy will follow the schema outlined in the study protocol.

Progress: The one patient entered on this study has expired. Groupwide, there is no survival difference. The addition of cis-platinum appears to significantly influence response and progression-free interval.

# Detail Summary Sheet

|   |                            |                 |
|---|----------------------------|-----------------|
| Date: 16 Nov 83   | Proj No: GOG 48            | Status: Ongoing |
| TITLE: A Study of Progestin Therapy and a Randomized Comparison of Adriamycin vs Adriamycin + Cyclophosphamide in Patients with Advanced Endometrial Carcinoma After Hormonal Failure, Phase III. |                            |                 |
| Start Date FY 80  | Est Comp Date: Unknown     |                 |
| Principal Investigator  | Facility                   |                 |
| Charles Capen, M.D., LTC, MC  | Brooke Army Medical Center |                 |
| Dept/Sec  | Associate Investigators:   |                 |
| Department of Obstetrics and Gynecology   |                            |                 |
| Key Words:  |                            |                 |
| Endometrial Carcinoma   |                            |                 |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|                            |                            | Continue                 |

Objectives: To evaluate the response of advanced or recurrent endometrial carcinoma to oral progestins in patients who have received no prior hormonal therapy.

To compare a combination of adriamycin and cyclophosphamide to adriamycin alone as therapy for advanced or recurrent endometrial carcinoma which no longer responds to or has failed to respond to progestins in patients who have received no prior cytotoxic drugs.

Technical Approach: To be eligible for entry on this study, all patients must have documented primary Stage III, primary Stage IV, recurrent or residual endometrial adenocarcinoma, adenoacanthoma or adenosquamous carcinoma. Those patients with positive cytology as evidence of spread are eligible as nonmeasurable disease cases.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study. Groupwide, there is no significant difference when survival and progression-free interval are compared by treatment.

# Detail Summary Sheet

|  |                            |                 |
|--|----------------------------|-----------------|
| Date: 16 Nov 83  | Proj No: GOG 49            | Status: Ongoing |
| TITLE: A Surgical-Pathologic Study of Women with Invasive Carcinoma of the Cervix Stage IB and Randomly Assigned Radiation Therapy versus no Further Therapy in Selected Patients. |                            |                 |
| Start Date FY 81   | Est Comp Date: Unknown     |                 |
| Principal Investigator   | Facility                   |                 |
| Charles Capen, M.D., LTC, MC   | Brooke Army Medical Center |                 |
| Dept/Sec   | Associate Investigators:   |                 |
| Department of Obstetrics and Gynecology  |                            |                 |
| Key Words:   |                            |                 |
| Invasive carcinoma   |                            |                 |
| Cervix   |                            |                 |

|  |                  |                          |
|--|------------------|--------------------------|
| Accumulative MEDCASE   | Est Accumulative | Periodic                 |
| Cost:  | OMA Cost:        | Review Results: Continue |
| Objectives: To determine by observations of the 5-year survival and disease-free interval, the validity of current FIGO staging to the histopathologic prognostic factors of size of lesion, location of lesion, depth of invasion of tumor, in millimeters, histology and grade, growth pattern, and site and number of positive lymph nodes in Stage IB carcinoma of the cervix. |                  |                          |

To rapidly accumulate prospectively significant surgical pathologic data which would expedite development of further protocols.

To determine morbidity of primary radical surgical therapy.

To determine if radiation therapy will improve survival in selected patients with positive nodes.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive carcinoma of the cervix (squamous cell, adenocarcinoma or adenosquamous) are eligible. Patients must have had a pelvic and para-aortic lymphadenectomy.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study. Groupwide, it is too early to evaluate.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: GOG 50 Status: Ongoing

## TITLE:

A Study of Adriamycin as Postoperative Therapy for Ovarian Sarcoma, Primary or Recurrent, with No Prior Chemotherapy, Phase III.

Start Date FY 81

Est Comp Date: Unknown

Principal Investigator

Facility

Charles Capen, M.D., LTC, MC

Brooke Army Medical Center

Dept/Sec

Associate Investigators:

Department of Obstetrics and Gynecology

Key Words:

Ovarian sarcoma

Adriamycin

Accumulative MEDCASE

Est Accumulative

Periodic

Cost:

OMA Cost:

Review Results:

Continue

Objectives: To evaluate the efficacy of Adriamycin in the treatment of ovarian sarcomas, primary or recurrent, through historic controls.

To accumulate additional surgical-pathological data relative to ovarian sarcomas.

Technical Approach: All patients must have histologically confirmed primary Stage I-IV or recurrent ovarian sarcoma. Optimal reductive surgery is required for cases with advanced disease, whether primary or recurrent. Patients may have measurable disease, non-measurable disease or no residual disease postoperatively. The endometrium must be examined to exclude an endometrial origin of tumor.

Patients with primary Stage I-IV disease must be entered and protocol therapy begun within six weeks of surgery. Patients with recurrent disease must be entered and protocol therapy begun within six weeks of documented recurrence.

Progress: No patients have been registered on this study. Groupwide, it is too early to report any meaningful data.

# Detail Summary Sheet

|   |  |                                   |
|---|--|-----------------------------------|
| Date: 16 Nov 83   | Proj No: GOG 51                        | Status: Ongoing                   |
| TITLE: A Randomized Comparison of Droperidol versus THC in the Treatment of Nausea and Vomiting Produced by Cis-platinum Chemotherapy for Gynecologic Malignancies. |  |                                   |
| Start Date FY 81  | Est Comp Date: Unknown                 |                                   |
| Principal Investigator<br>Charles Capen, M.D., LTC, MC  | Facility<br>Brooke Army Medical Center |                                   |
| Dept/Sec<br>Department of Obstetrics and Gynecology   | Associate Investigators:               |                                   |
| Key Words:<br>THC (Delta-9-Tetrahydrocannabinol)<br>Droperidol (Dehydrobenzperidol)<br>Cis-platinum   |  |                                   |
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost:             | Periodic Review Results: Continue |
| Objective: To evaluate the effectiveness of Droperidol and THC as anti-emetic agents in chemotherapy of gynecologic malignancies treated with Cis-platinum.         |  |                                   |

Technical Approach: Patients with gynecologic malignancies who receive Cis-platinum as a single agent are eligible. Patients will be randomized to one of two treatment groups. Group 1 will receive THC by mouth during two courses of chemotherapy, and then take droperidol by injection for two chemotherapy courses. Group 2 will receive droperidol by injection for two chemotherapy courses and then THC by mouth during two courses of chemotherapy.

Progress: No patients have been enrolled in this study. Groupwide, no reportable data are available at this time.

# Detail Summary Sheet

|   |           |                            |         |         |         |
|---|-----------|----------------------------|---------|---------|---------|
| Date:   | 16 Nov 83 | Proj No:                   | GOG 52  | Status: | Ongoing |
| TITLE: A Phase III Randomized Study of Cyclophosphamide plus Adriamycin plus Platinol (Cis-platinum) vs Cyclophosphamide plus Platinol in Patients with Optimal Stage III Ovarian Adenocarcinoma. |           |                            |         |         |         |
| Start Date  | Oct 81    | Est Comp Date:             | Unknown |         |         |
| Principal Investigator  |           | Facility                   |         |         |         |
| Charles Capen, M.D., LTC, MC  |           | Brooke Army Medical Center |         |         |         |
| Dept/Sec  |           | Associate Investigators:   |         |         |         |
| Department of Obstetrics and Gynecology   |           |                            |         |         |         |
| Key Words:  |           |                            |         |         |         |
| Ovarian adenocarcinoma  |           |                            |         |         |         |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objective: To determine in "optimal" Stage III ovarian adenocarcinoma, if the addition of adriamycin to cyclophosphamide plus cis-platinum (platinol) improves progression-free interval, frequency of negative second-look laparotomy and survival. |                            |                          |

Technical Approach: Patients with proven primary Stage III ovarian adenocarcinoma (serous, mucinous, endometrioid, undifferentiated carcinoma, mixed epithelial carcinoma or clear cell) confined to the abdominal cavity and its peritoneal surfaces with residual tumor masses after surgery no larger than 1 cm in diameter are eligible. Entry must be no more than six weeks post-operative.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been registered on this study. Groupwide, it is too early to report any meaningful data.

# Detail Summary Sheet

|   |                            |                |         |         |         |
|---|----------------------------|----------------|---------|---------|---------|
| Date:   | 16 Nov 83                  | Proj No:       | GOG 56  | Status: | Ongoing |
| TITLE: A Randomized Comparison of Hydroxyurea vs Misonidazole as an Adjunct to Radiation Therapy in Patients with Stages IIB, III and IVA Carcinoma of the Cervix and Negative Para-Aortic Nodes. |                            |                |         |         |         |
| Start Date  | Nov 81                     | Est Comp Date: | Unknown |         |         |
| Principal Investigator  | Facility                   |                |         |         |         |
| Charles Capen, M.D., LTC, MC  | Brooke Army Medical Center |                |         |         |         |
| Dept/Sec  | Associate Investigators:   |                |         |         |         |
| Department of Obstetrics and Gynecology   |                            |                |         |         |         |
| Key Words:  |                            |                |         |         |         |
| Carcinoma of cervix   |                            |                |         |         |         |
| Para-aortic nodes   |                            |                |         |         |         |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To determine whether hydroxyurea or misonidazole is superior as a potentiation of radiation therapy in advanced cervical cancer. |                            |                          |

To compare the toxicity of hydroxyurea vs misonidazole when given concurrently with radiotherapy.

Technical Approach: All patients with primary, previously untreated, histologically confirmed invasive squamous cell carcinoma of the uterine cervix, clinical stages IIB through IVA confined to the pelvis will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled in the study. No reportable data are available from GOG.

# Detail Summary Sheet

|   |                            |                 |
|---|----------------------------|-----------------|
| Date: 16 Nov 83   | Proj No: GOG 59            | Status: Ongoing |
| TITLE: A Randomized Comparison of Extended Field Radiation Therapy and Hydroxy-urea Followed by Cisplatin or No Further Therapy in Patients with Cervical Squamous Cell Carcinoma Metastatic to High Common Iliac...Lymph Nodes--III. |                            |                 |
| Start Date Nov 81   | Est Comp Date: Unknown     |                 |
| Principal Investigator  | Facility                   |                 |
| Charles Capen, M.D., LTC, MC  | Brooke Army Medical Center |                 |
| Dept/Sec  | Associate Investigators:   |                 |
| Department of Obstetrics and Gynecology   |                            |                 |
| Key Words:  |                            |                 |
| Cervical squamous cell carcinoma  |                            |                 |
| Metastatic  |                            |                 |
| Common iliac lymph nodes  |                            |                 |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine if cis-diamminedichloroplatinum, cisplatin, given in an adjuvant setting will decrease the risk of geographic failure or improve the survival rate or progression-free interval in patients with squamous carcinoma of the cervix with metastases to high common iliac and/or para-aortic lymph nodes, proven by either histologic or cytologic means.

To evaluate the role of scalene fat pad biopsy in this group of patients before initiation of extended field irradiation therapy.

To accumulate clinical/surgical/pathologic data on this high-risk group of patients to expedite development of further protocols.

Technical Approach: All patients with primary, previously untreated, histologically confirmed, invasive squamous cell carcinoma of the uterine cervix, all clinical stages, with metastasis to high common iliac or para-aortic lymph nodes proven by cytologic or histologic means are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study. It is too early for reportable data from GOG.



# Detail Summary Sheet

|   |                            |                |         |         |         |
|---|----------------------------|----------------|---------|---------|---------|
| Date:   | 16 Nov 83                  | Proj No:       | GOG 60  | Status: | Ongoing |
| TITLE: A Randomized Study of Doxorubicin plus Cyclophosphamide plus Cisplatin vs Doxorubicin plus Cyclophosphamide plus Cisplatin plus BCG in Patients with Advanced Suboptimal Ovarian Adenocarcinoma, Stage III and IV. |                            |                |         |         |         |
| Start Date  | Nov 81                     | Est Comp Date: | Unknown |         |         |
| Principal Investigator  | Facility                   |                |         |         |         |
| Charles Capen, M.D., LTC, MC  | Brooke Army Medical Center |                |         |         |         |
| Dept/Sec  | Associate Investigators:   |                |         |         |         |
| Department of Obstetrics and Gynecology   |                            |                |         |         |         |
| Key Words:  |                            |                |         |         |         |
| Ovarian adenocarcinoma  |                            |                |         |         |         |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objectives: To determine if the addition of BCG to doxorubin (adriamycin) plus cyclophosphamide plus cisplatin improves remission rate, remission duration, or survival in suboptimal Stage III and IV ovarian adenocarcinoma. |                            |                          |

To determine the frequency and duration of true complete remission using these regimens as judged at second-look laparotomy.

Technical Approach: Patients with established suboptimal Stage III and IV ovarian epithelial cancer are eligible. All patients must have optimal surgery and appropriate tissue for histologic evaluation, as detailed in protocol GOG 41.

therapy will follow the schema outlined in the study protocol.

Progress: No patients have been enrolled in this study. No reportable data are available from GOG.

# Detail Summary Sheet

|  |                            |                 |
|--|----------------------------|-----------------|
| Date: 16 Nov 83  | Proj No: GOG 61            | Status: Ongoing |
| TITLE: Randomized Study of Cis-platinum + Cyclophosphamide vs Hexamethylmelamin after Second-Look Surgery in Nonmeasurable Stage III Ovarian Adenocarcinoma Partially Responsive to...Cis-platinum and Cyclophosphamide. |                            |                 |
| Start Date: Nov 81   | Est Comp Date: Unknown     |                 |
| Principal Investigator   | Facility                   |                 |
| Charles Capen, M.D., LTC, MC   | Brooke Army Medical Center |                 |
| Dept/Sec   | Associate Investigators:   |                 |
| Department of Obstetrics and Gynecology  |                            |                 |
| Key Words:   |                            |                 |
| Ovarian adenocarcinoma   |                            |                 |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objective: To determine, in nonmeasurable but residual Stage III ovarian adenocarcinoma partially responsive after treatment with regimens containing cis-platinum and cyclophosphamide, if the progression-free interval and survival are improved by continuing cyclophosphamide plus cis-platinum or by changing treatment to hexamethylmelamine. |                            |                          |

Technical Approach: Patients who have been diagnosed as Stage III ovarian cancer and who have had residual disease found at second-look laparotomy may be eligible. A patient who began with measurable disease and achieved a clinical complete response, but then at second look was found to have residual disease after treatment with regimens containing cis-platinum plus cytoxan would be eligible. A patient who originally had nonmeasurable disease and who at the time of second look has less volume of disease than was described at the time of the original surgery or in whom there has been no change in the volume of disease would be eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study. No reportable data are available from GOG.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: 7601 Status: Ongoing

## TITLE:

Ovarian Cancer Study Group Protocol for Selected Stage IAI - IBI Ovarian Cancer (Well and Moderately Differentiated).

|   |       |                            |         |
|---|-------|----------------------------|---------|
| Start Date                              | FY 79 | Est Comp Date:             | Unknown |
| Principal Investigator                  |       | Facility                   |         |
| Charles Capen, M.D., LTC, MC            |       | Brooke Army Medical Center |         |
| Dept/Sec                                |       | Associate Investigators:   |         |
| Department of Obstetrics and Gynecology |       |                            |         |
| Key Words:                              |       |                            |         |
| Ovarian cancer                          |       |                            |         |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To define the natural history (relapse rate, relapse site, relapse free survival) of patients treated by surgery alone.

To determine whether prophylactic, adjuvant chemotherapy with melphalan alters the natural history.

To study the effect of various potential prognostic factors (stratification factors) on the natural history of patients treated by each form of therapy.

To determine the patterns of relapse for each form of therapy.

To establish the value of various staging parameters on the stage of disease and its natural history.

Technical Approach: All eligible patients must have a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous, and those listed in Appendix I of the protocol. After definitive staging procedure, if the patient is a selective Stage IAI, or IBI, and the histologic grade is well or moderately differentiated, the patient is eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been registered on this study. No reportable data are available from GOG.

# Detail Summary Sheet

|  |                            |                |         |         |         |
|--|----------------------------|----------------|---------|---------|---------|
| Date:  | 16 Nov 83                  | Proj No:       | 7602    | Status: | Ongoing |
| TITLE:   |                            |                |         |         |         |
| Ovarian Cancer Study Group Protocol for All Stage IC and II (A,B,C) and Selected Stage IAii and IBii Ovarian Cancer. |                            |                |         |         |         |
| Start Date   | FY 79                      | Est Comp Date: | Unknown |         |         |
| Principal Investigator   | Facility                   |                |         |         |         |
| Charles Capen, M.D., LTC, MC   | Brooke Army Medical Center |                |         |         |         |
| Dept/Sec   | Associate Investigators:   |                |         |         |         |
| Department of Obstetrics and Gynecology  |                            |                |         |         |         |
| Key Words:   |                            |                |         |         |         |
| Ovarian cancer   |                            |                |         |         |         |

|                      |                  |                          |
|----------------------|------------------|--------------------------|
| Accumulative MEDCASE | Est Accumulative | Periodic                 |
| Cost:                | OMA Cost:        | Review Results: Continue |

Objectives: To define the natural history (relapse rate, relapse sites, relapse free survival, regression rate, duration of regression) of patients treated by surgery plus either chemotherapy or chemotherapy plus radiation therapy.

To study the effect of various potential prognostic factors (stratification factors) on the natural history of patients treated by each form of therapy.

To determine the patterns of relapse for each form of therapy.

To establish the value of various staging parameters on the stage of disease and its natural history.

Technical Approach: All eligible patients must have a histopathologic diagnosis of common epithelial ovarian cancer of one of the following types: serous, mucinous or one of the types identified in Appendix I of the study protocol. After a definitive staging procedure, if the patient is Stage II-A, II-B, II-C, I-Aii, I-Bii, or I-Ai or I-Bi with poorly differentiated tumors, she is eligible for this study. The patient must have had no previous treatment except surgical therapy.

Randomization and therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered on this study. Groupwide, patient accrual has been slow. No reportable data are available.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: PVSG-12 Status: Ongoing

## TITLE:

Hydroxyurea in Thrombosis.

|  |                            |                            |
|--|----------------------------|----------------------------|
| Start Date                                 | FY 80                      | Est Comp Date:             |
| Principal Investigator                     |                            | Facility                   |
| Glenn M. Mills, M.D., MAJ, MC              |                            | Brooke Army Medical Center |
| Dept/Sec                                   |                            | Associate Investigators:   |
| Department of Medicine/Hematology-Oncology |                            |                            |
| Key Words:                                 |                            |                            |
| Thrombocytopenia                           |                            |                            |
| Myelofibrosis-myeloid metaplasia           |                            |                            |
| Myeloproliferative disease                 |                            |                            |
| Accumulative MEDCASE Cost:                 | Est Accumulative OMA Cost: | Periodic Review Results:   |

Objective: To evaluate the efficacy of hydroxyurea in preventing and controlling the symptoms of thrombosis and bleeding with 1) the clinical entity primary thrombocytopenia, 2) those patients with myelofibrosis-myeloid metaplasia with elevated platelet counts, and 3) those patients with unclassified myeloproliferative disease with elevated platelet counts.

Technical Approach: In order to be eligible for entry on this study, the patient must meet the following criteria: 1) Absence of Philadelphia chromosome, 2) Absence of an increased red cell mass, 3) Bone marrow which shows marked megakaryocytic hyperplasia and abundant platelet clumps, 4) Thrombosis not secondary to some identifiable cause, i.e., infection, cancer etc., and 5) Patient must not have had a pre-existing cancer, other than skin cancer.

Therapy will follow the schema outlined in the study protocol.

Progress: Six patients remain on the study. Study closed to any future randomization.

# Detail Summary Sheet

Date: 16 Nov 83 Proj No: PVSG-13 Status: Terminated  
 TITLE: Study of the Clinical Features and Natural History of Asymptomatic Patients with Myeloproliferative Disorders.  
 Start Date FY 79 Est Comp Date:  
 Principal Investigator Facility  
 Glenn M. Mills, M.D., MAJ, MC Brooke Army Medical Center  
 Dept/Sec Associate Investigators:  
 Department of Medicine/Hematology-Oncology  
 Key Words:  
 Myeloproliferative disorder

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To obtain a clinical and laboratory data base on patients with myeloproliferative disorders prior to the time they require treatment under other MPD protocols.

To define the natural course of the disease as to the development of:  
 a) splenomegaly, b) progressive fibrosis, c) leukemic conversion, d) thrombo-embolic complications, and e) other neoplasm.

To demonstrate the development of cytogenetic and pathologic abnormalities in bone marrow and peripheral blood.

To establish predictors of a more symptomatic stage of the disease.

Technical Approach: All newly diagnosed (less than one year), previously untreated patients (including patients transfused for a period of less than three months) considered to have one of the myeloproliferative disorders outlined in the protocol are eligible.

Progress: No patients were entered on this study. Study terminated due to loss of grant.

# Detail Summary Sheet

Date: 16 Nov 81 Proj No: PVSG-15 Status: Terminated  
TITLE:

Efficacy Trial Using Cyproheptadine and Cimetidine for Pruritus in Polycythemia Vera

Start Date 10 Oct 81 Est Comp Date:

Principal Investigator Facility  
Glenn M. Mills, M.D., MAJ, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Medicine/Hematology-Oncology

Key Words:

Pruritus

Polycythemia Vera

| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
|--|----------------------------|--------------------------|
| Objective: To determine whether H <sub>1</sub> and H <sub>2</sub> blocking agents used concomitantly are efficacious in alleviating the pruritus of polycythemia vera. |                            |                          |

Technical Approach: Any patient with polycythemia vera in remission, i.e., Hct. of 40-45%, following treatment who suffers from persistent pruritus which worsens with bathing or showering and which does not antedate the onset of symptoms of polycythemia vera is eligible for this protocol.

Progress: No patients were entered on this study. The study was terminated by the Group because the treatment was found to be ineffective.

Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7376 Status: Ongoing

TITLE:

Evaluation of Natural History of Histiocytosis X in Childhood

Start Date Feb 81 Est Comp Date: Unknown

Principal Investigator Facility

Terry E. Pick, M.D., LTC, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Pediatrics

Key Words:

Histiocytosis X

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: To obtain information about the natural history of all forms of histiocytosis X and histiocytic medullary reticulosis.

Technical Approach: All new patients with a biopsy-proven diagnosis of histiocytosis X should be registered for the study.

This study involves reporting on the results of examinations, tests, and treatment during the course of the disease. The examinations and tests are outlined in the study protocol.

Progress: One patient has been registered on this study.



# Detail Summary Sheet

|   |           |                            |          |         |         |
|---|-----------|----------------------------|----------|---------|---------|
| Date:   | 22 Nov 83 | Proj No:                   | POG 7612 | Status: | Ongoing |
| TITLE:  |           |                            |          |         |         |
| MOPP + Bleo vs A-COPP with IF RT in Stage III Hodgkin's Disease in Children |           |                            |          |         |         |
| Start Date  | 25 Sep 81 | Est Comp Date: Unknown     |          |         |         |
| Principal Investigator  |           | Facility                   |          |         |         |
| Terry E. Pick, M.D., LTC, MC  |           | Brooke Army Medical Center |          |         |         |
| Dept/Sec  |           | Associate Investigators:   |          |         |         |
| Department of Pediatrics  |           |                            |          |         |         |
| Key Words:  |           |                            |          |         |         |
| Hodgkin's disease   |           |                            |          |         |         |

|  |                  |                 |
|--|------------------|-----------------|
| Accumulative MEDCASE   | Est Accumulative | Periodic        |
| Cost:  | OMA Cost:        | Review Results: |
| Objective: To compare the effectiveness of IF radiotherapy plus MOPP + Bleo with IF radiotherapy plus A-COPP chemotherapy in treating Stage III Hodgkin's disease in children. |                  |                 |

To determine the patient tolerance of the two chemotherapy regimens in terms of immediate toxicity including the incidence of infection.

Technical Approach: All children, 18 years or younger, with Stage III Hodgkin's disease including extranodal presentations + constitutional symptoms, regardless of specific with no prior therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered into the study. It appears that this treatment regimen is effective in controlling the disease.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7621 Status: Ongoing

## TITLE:

MOPP vs OPP in the Treatment of Children with Recurrent Brain Tumors

|                              |        |                            |         |
|------------------------------|--------|----------------------------|---------|
| Start Date                   | Feb 81 | Est Comp Date:             | Unknown |
| Principal Investigator       |        | Facility                   |         |
| Terry E. Pick, M.D., LTC, MC |        | Brooke Army Medical Center |         |
| Dept/Sec                     |        | Associate Investigators:   |         |
| Department of Pediatrics     |        |                            |         |
| Key Words:                   |        |                            |         |
| Brain tumor                  |        |                            |         |

|                            |                            |                          |          |
|----------------------------|----------------------------|--------------------------|----------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: | Continue |
|----------------------------|----------------------------|--------------------------|----------|

Objective: To determine and compare response to MOPP or OPP in children with recurrent brain tumors.

Technical Approach: All patients who have been diagnosed to have a central nervous system tumor, and who have previously received maximally allowable dose of radiotherapy will be eligible for randomization which will require no prior therapy with either nitrogen mustard or BCNU. Patients must be 18 years of age or under at the time of diagnosis.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7712 Status: Ongoing  
TITLE:

Comparison of Treatment Regimens for the First CNS Relapse in Children with Acute Lymphocytic Leukemia - CNS #6

|                        |                              |                          |                            |
|------------------------|------------------------------|--------------------------|----------------------------|
| Start Date             | 25 Sep 81                    | Est Comp Date:           | Unknown                    |
| Principal Investigator | Terry E. Pick, M.D., LTC, MC | Facility                 | Brooke Army Medical Center |
| Dept/Sec               | Department of Pediatrics     | Associate Investigators: |                            |
| Key Words:             | Acute lymphocytic leukemia   |                          |                            |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To compare two therapies for CNS leukemia with respect to length of CNS remission and CNS toxicity.

Technical Approach: Patients less than 21 years of age at time of initial diagnosis with first CNS relapse who have not had more than one marrow relapse are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been entered into this study.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7799 Status: Ongoing

## TITLE:

Rare Tumor Registry for Childhood Solid Tumor Malignancies

|                              |           |                            |         |
|------------------------------|-----------|----------------------------|---------|
| Start Date                   | 25 Sep 81 | Est Comp Date:             | Unknown |
| Principal Investigator       |           | Facility                   |         |
| Terry E. Pick, M.D., LTC, MC |           | Brooke Army Medical Center |         |
| Dept/Sec                     |           | Associate Investigators:   |         |
| Department of Pediatrics     |           |                            |         |
| Key Words:                   |           |                            |         |
| Solid tumor                  |           |                            |         |

|                      |                  |                          |
|----------------------|------------------|--------------------------|
| Accumulative MEDCASE | Est Accumulative | Periodic                 |
| Cost:                | OMA Cost:        | Review Results: Continue |

Objectives: To collect natural history data on malignancies which occur so rarely that large series of patients cannot be accumulated at any single institution.

To evaluate therapies in those groups of rare tumors in which fair numbers of cases can be accrued.

Technical Approach: Any child under the age of 18 years at diagnosis with a rare solid tumor is eligible for the study.

Progress: Two patients have been entered on this study. It is too early to report any significant results.

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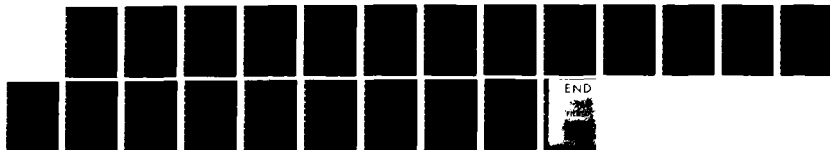
ANNUAL RESEARCH PROGRESS REPORT FOR FISCAL YEAR 1983  
(U) BROOKE ARMY MEDICAL CENTER FORT SAM HOUSTON TX  
J H ANDERSON 01 OCT 83

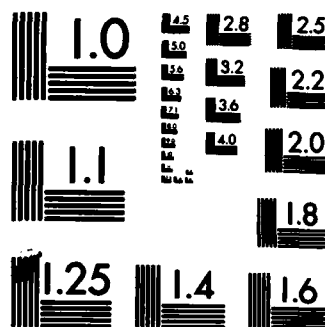
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MICROCOPY RESOLUTION TEST CHART  
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# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7812 Status: Closed

## TITLE:

Anguidine in Central Nervous System Tumors

|                               |                            |                            |
|-------------------------------|----------------------------|----------------------------|
| Start Date                    | 25 Sep 81                  | Est Comp Date:             |
| Principal Investigator        |                            | Facility                   |
| Terry E. Pick, M.D., LTC, MC  |                            | Brooke Army Medical Center |
| Dept/Sec                      |                            | Associate Investigators:   |
| Department of Pediatrics      |                            |                            |
| Key Words:                    |                            |                            |
| Central nervous system tumors |                            |                            |
| Accumulative MEDCASE Cost:    | Est Accumulative OMA Cost: | Periodic Review Results:   |

Objective: To determine the anti-tumor activity of anguidine in the treatment of malignant brain tumors in children and adolescents relative to clinical response and survival.

Technical Approach: Patients with histologically confirmed primary CNS tumors as follows are eligible: Astrocytoma, Grades III and IV; ependymoma, oligodendroglioma; medulloblastoma and patients under 21 years of age with clinical diagnosis of recurrent brain stem glioma following radiation therapy are eligible. Patients must not be eligible for protocols of higher priority or treatment of proven or likely higher efficacy.

Progress: This study has been closed to new entries. No patients from BAMC were entered into this study.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7818 Status: Closed

## TITLE:

Rubidazone in Children with ALL and AML in Relapse

|                              |                            |                            |
|------------------------------|----------------------------|----------------------------|
| Start Date                   | 25 Sep 81                  | Est Comp Date:             |
| Principal Investigator       |                            | Facility                   |
| Terry E. Pick, M.D., LTC, MC |                            | Brooke Army Medical Center |
| Dept/Sec                     |                            | Associate Investigators:   |
| Department of Pediatrics     |                            |                            |
| Key Words:                   |                            |                            |
| Acute lymphocytic leukemia   |                            |                            |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results:   |

Objective: To determine the clinical efficacy and toxicity of rubidazone when used for the induction of remission in children with acute leukemia.

Technical Approach: Patients 21 years of age or under with acute leukemia in relapse, not eligible for protocols of higher priority, are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed to new entires. No patients from BAMC were registered on this protocol.



# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7829 Status: Ongoing

## TITLE:

Comparison of Two Dose Regimens of Intrathecal Methotrexate for CNS Leukemia, Phase II

|  |  |
|--|--|
| Start Date 25 Sep 81                                   | Est Comp Date: Unknown                 |
| Principal Investigator<br>Terry E. Pick, M.D., LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department of Pediatrics                   | Associate Investigators:               |
| Key Words:<br>CNS leukemia                             |  |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To compare the toxicity, response rates and duration of response obtained by using a two dose regimen of intrathecal methotrexate.

Technical Approach: Patients under the age of 21 with CNS leukemia in relapse who are not known to be resistant to intrathecal methotrexate are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this protocol.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7834 Status: Ongoing

## TITLE:

Second Induction Maintenance in Acute Lymphocytic Leukemia, Phase III

|                              |           |                            |
|------------------------------|-----------|----------------------------|
| Start Date                   | 25 Sep 81 | Est Comp Date: Unknown     |
| Principal Investigator       |           | Facility                   |
| Terry E. Pick, M.D., LTC, MC |           | Brooke Army Medical Center |
| Dept/Sec                     |           | Associate Investigators:   |
| Department of Pediatrics     |           |                            |
| Key Words:                   |           |                            |
| Acute lymphocytic leukemia   |           |                            |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objective: To determine in children in the first relapse of ALL in remission duration which can be achieved following an intensive and aggressive induction regimen and maintenance. |                            |                          |

Technical Approach: Patients under the age of 21 years in their first CNS and/or extramedullary and/or bone marrow relapse with acute lymphocytic leukemia are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: One patient has been entered into this study. It is too early to make any positive or negative statement regarding response to therapy.

# Detail Summary Sheet

|  |                            |                 |
|--|----------------------------|-----------------|
| Date: 22 Nov 83  | Proj No: POG 7837          | Status: Ongoing |
| TITLE: Evaluation of Systemic Therapy for Children with T Cell Acute Lymphatic Leukemia, Phase III |                            |                 |
| Start Date 25 Sep 81   | Est Comp Date: Unknown     |                 |
| Principal Investigator   | Facility                   |                 |
| Terry E. Pick, M.D., LTC, MC   | Brooke Army Medical Center |                 |
| Dept/Sec   | Associate Investigators:   |                 |
| Department of Pediatrics   |                            |                 |
| Key Words:   |                            |                 |
| Acute lymphatic leukemia   |                            |                 |
| T-cell   |                            |                 |

|   |                            |                          |
|---|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:  | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objective: To evaluate the effectiveness of a program of sequential systemic chemotherapy plus CNS treatment for children with untreated T-cell leukemia. |                            |                          |

Technical Approach: Patients under the age of 21 with a diagnosis of T-cell leukemia as defined by SWOG 7865 including all patients who have 20% or greater E-rosetting leukemia cells are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: Four patients have been registered on this study. Two are alive and doing well and two have expired.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7843 Status: Ongoing  
 TITLE:

Evaluation of Rubidazone in the Treatment of Children with Solid Tumors,  
 Phase II

|                              |           |                            |         |
|------------------------------|-----------|----------------------------|---------|
| Start Date                   | 25 Sep 81 | Est Comp Date:             | Unknown |
| Principal Investigator       |           | Facility                   |         |
| Terry E. Pick, M.D., LTC, MC |           | Brooke Army Medical Center |         |
| Dept/Sec                     |           | Associate Investigators:   |         |
| Department of Pediatrics     |           |                            |         |
| Key Words:                   |           |                            |         |
| Solid tumor                  |           |                            |         |

|  |                            |                          |
|--|----------------------------|--------------------------|
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results: |
| Objective: To determine the clinical efficacy of rubidazone in the treatment of malignant tumors in children with and without previous anthracycline therapy and to determine the toxicity of this drug in children with solid tumors. |                            |                          |

Technical Approach: All patients under the age of 21 with a measurable tumor lesion, resistant to conventional chemotherapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

# Detail Summary Sheet

|  |                            |                            |          |         |         |
|--|----------------------------|----------------------------|----------|---------|---------|
| Date:  | 22 Nov 83                  | Proj No:                   | POG 7895 | Status: | Ongoing |
| TITLE:   |                            |                            |          |         |         |
| Multimodal Therapy for Management of Primary Non-Metastatic Ewing's Sarcoma of Pelvic and Sacral Bones.  |                            |                            |          |         |         |
| Start Date   | 25 Sep 81                  | Est Comp Date:             |          |         |         |
| Principal Investigator   |                            | Facility                   |          |         |         |
| Terry E. Pick, M.D., LTC, MC   |                            | Brooke Army Medical Center |          |         |         |
| Dept/Sec   |                            | Associate Investigators:   |          |         |         |
| Department of Pediatrics   |                            |                            |          |         |         |
| Key Words:   |                            |                            |          |         |         |
| Ewing's sarcoma  |                            |                            |          |         |         |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results:   |          |         |         |
| Objective: To determine the effectiveness of high dose intermittent chemotherapy to prevent local recurrence and/or metastases with surgical resection and a uniform radiation therapy regimen to control local disease. |                            |                            |          |         |         |

Technical Approach: Patients with biopsy-proven localized Ewing's sarcoma with no prior chemotherapy and/or radiation therapy are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7901 Status: Ongoing

## TITLE:

Rescue Therapy for Non-CNS Extramedullary Disease in Children with Acute Lymphoblastic Leukemia, Phase III

Start Date: 27 Jan 83 Est Comp Date: Unknown

Principal Investigator Facility

Terry E. Pick, M.D., LTC, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Pediatrics

Key Words:

Acute lymphoblastic leukemia

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To administer effective local therapy for non-CNS extramedullary disease occurring during marrow remission or marrow relapse in children with acute lymphocytic leukemia (ALL).

To prevent imminent marrow and/or CNS relapse in those children developing EMD during complete remission status.

To restore complete marrow remission and protect the CNS of children developing EMD during marrow relapse.

To restore complete CNS remission and prevent imminent marrow relapse in children developing EMD during CNS relapse.

To restore complete marrow remission and CNS remission in children developing EMD during bone marrow and CNS relapse.

To accumulate data on 1) the relative incidence of EMD at various sites in children with ALL, and 2) the prognostic implications on EMD at various sites.

Technical Approach: Children less than 21 years of age at time of diagnosis, with ALL are eligible for emd "rescue" therapy when the diagnosis of EMD has been established.

Progress: Three patients have been registered on this study. It is too early to report any significant results.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 7909 Status: Ongoing  
 TITLE:

Evaluation of MOPP Adjuvant Chemotherapy in the Treatment of Localized Medulloblastoma and Ependymoma

|  |  |
|--|--|
| Start Date May 81                                      | Est Comp Date: Unknown                 |
| Principal Investigator<br>Terry E. Pick, M.D., LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department of Pediatrics                   | Associate Investigators:               |
| Key Words:<br>Medulloblastoma<br>Ependymoma            |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objective: To evaluate the efficacy and toxicity of the MOPP adjuvant chemotherapy in the prevention of local recurrence of distant metastasis in children with localized medulloblastoma and ependymoma.

Technical Approach: Patients between 1 and 21 years (inclusive) with histologically proven medulloblastoma and ependymoma are eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: Two patients have been entered into this study. One continues to respond fairly well to therapy, and the other has expired.

# Detail Summary Sheet

|  |                            |                            |          |         |        |
|--|----------------------------|----------------------------|----------|---------|--------|
| Date:  | 22 Nov 83                  | Proj No:                   | POG 7919 | Status: | Closed |
| TITLE:   |                            |                            |          |         |        |
| Evaluation of m-AMSA in Children with Acute Leukemia and Non-Hodgkins in Relapse |                            |                            |          |         |        |
| Start Date   | Nov 80                     | Est Comp Date:             |          |         |        |
| Principal Investigator   |                            | Facility                   |          |         |        |
| Terry E. Pick, M.D., LTC, MC   |                            | Brooke Army Medical Center |          |         |        |
| Dept/Sec   |                            | Associate Investigators:   |          |         |        |
| Department of Pediatrics   |                            |                            |          |         |        |
| Key Words:   |                            |                            |          |         |        |
| Acute leukemia   |                            |                            |          |         |        |
| Non-Hodgkin's lymphoma   |                            |                            |          |         |        |
| Accumulative MEDCASE Cost:   | Est Accumulative OMA Cost: | Periodic Review Results:   |          |         |        |

Objectives: To determine the clinical efficacy of m-AMSA, as indicated by the induction of partial or complete remission, in pediatric patients with acute leukemia or non-Hodgkin's lymphoma in relapse.

To further assess the toxicity of m-AMSA in children.

Technical Approach: All patients with acute leukemia (lymphocytic and non-lymphocytic) or non-Hodgkin's lymphoma in relapse who are 18 years of age or under at the time of diagnosis, who are not eligible for protocols of higher priority and who are resistant to standard forms of therapy, will be eligible for this study.

Therapy will follow the schema outlined in the study protocol.

Progress: This study has been closed to new entries. No patients from BAMC were enrolled on this protocol.



# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 8000 Status: Ongoing

TITLE:  
National Wilms' Tumor Study, III

|  |  |
|--|--|
| Start Date 25 Sep 81                                   | Est Comp Date: Unknown                 |
| Principal Investigator<br>Terry E. Pick, M.D., LTC, MC | Facility<br>Brooke Army Medical Center |
| Dept/Sec<br>Department of Pediatrics                   | Associate Investigators:               |
| Key Words:<br>Wilms' tumor                             |  |

|                            |                            |                                   |
|----------------------------|----------------------------|-----------------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: Continue |
|----------------------------|----------------------------|-----------------------------------|

Objectives: To gain better understanding of Wilms' tumor by gathering detailed information regarding gross and histologic morphology.

To refine methods of treatment according to staging.

To test treatment hypotheses by randomized, prospective clinical trials according to stage and histologic grade of disease.

To gather information about family cancer in an attempt to identify children and families at high risk.

To study the late consequences of successful treatment given for Wilms' tumor.

Technical Approach: Patients under the age of 15 with Wilms' tumor are eligible.

Progress: Four patients have been entered on this study. No reportable data are available at this time.

# Detail Summary Sheet

|   |                              |                |                          |                            |         |
|---|------------------------------|----------------|--------------------------|----------------------------|---------|
| Date:   | 22 Nov 83                    | Proj No:       | POG 8002                 | Status:                    | Ongoing |
| TITLE:  |                              |                |                          |                            |         |
| Combination Chemotherapy with Adriamycin, Cis-Platinum, Vincristine, and Cytosan in Children with Metastatic Neuroblastoma (Stage IV) |                              |                |                          |                            |         |
| Start Date  | 25 Sep 81                    | Est Comp Date: | Unknown                  |                            |         |
| Principal Investigator  | Terry E. Pick, M.D., LTC, MC |                | Facility                 | Brooke Army Medical Center |         |
| Dept/Sec  | Department of Pediatrics     |                | Associate Investigators: |                            |         |
| Key Words:  | Neuroblastoma, metastatic    |                |                          |                            |         |

|  |                  |                 |
|--|------------------|-----------------|
| Accumulative MEDCASE   | Est Accumulative | Periodic        |
| Cost:  | OMA Cost:        | Review Results: |
| Objectives: To delineate the toxicity of the combination of cytosan, vincristine, adriamycin and cis-platinum in children with metastatic neuroblastoma. |                  |                 |

To do a preliminary analysis of the therapeutic efficacy prior to consideration of this four-drug combination as front-line therapy for children with Stage IV neuroblastoma.

Technical Approach: Children from 1 to 18 years of age with biopsy-proven metastatic neuroblastoma (Stage IV) who have not had prior exposure to cis-platinum are eligible.

Therapy will follow the schema outlined in the study protocol.

Progress: No patients have been registered on this study.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 8035-6 Status: Ongoing

## TITLE:

Laboratory Subclassification and Evaluation of Treatment Regimens in Acute Lymphoid Leukemia of Childhood

|                              |           |                            |         |
|------------------------------|-----------|----------------------------|---------|
| Start Date                   | 27 Jan 83 | Est Comp Date:             | Unknown |
| Principal Investigator       |           | Facility                   |         |
| Terry E. Pick, M.D., LTC, MC |           | Brooke Army Medical Center |         |
| Dept/Sec                     |           | Associate Investigators:   |         |
| Department of Pediatrics     |           |                            |         |
| Key Words:                   |           |                            |         |
| Acute lymphoid leukemia      |           |                            |         |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objective: To determine if adding a high dose of a standard chemotherapy agent used in acute lymphocytic leukemia every 8 weeks and maintenance increases the chance of survival over the regular doses of standard chemotherapy drugs in the "good risk" patient.

To determine if one of three treatment regimens is better in treating the "poor risk" patient.

Technical Approach: Eligible patients will receive one of three treatment regimens. Regimen 1 consists of standard drugs given in the usual fashion with triple intrathecal medications given in the spinal fluid to preven CNS leukemia for three years. Regimen 2 consists of the standard chemotherapy agents plus high dose Methotrexate pulses during maintenance with triple intrathecal medications given in consolidation, and los dose intrathecal Methotrexate given for one year. Regimen 3 consists of pulses of a variety of courses of different agents that are superimposed upon the routine maintenance therapy plus triple intrathecal medications times three years to determine if these pulses of different chemotherapy agents can improve the outcome of this high risk group.

Progress: Eight patients have been enrolled on this study. Six are alive and thus far are responding to therapy. Two have expired.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 8075 Status: Ongoing

## TITLE:

Circulating Immune Complexes in Pediatric Malignancies

|                              |                            |
|------------------------------|----------------------------|
| Start Date 25 Sep 81         | Est Comp Date: Unknown     |
| Principal Investigator       | Facility                   |
| Terry E. Pick, M.D., LTC, MC | Brooke Army Medical Center |
| Dept/Sec                     | Associate Investigators:   |
| Department of Pediatrics     |                            |
| Key Words:                   |                            |
| Immune complex               |                            |

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To determine the incidence of elevated levels of circulating immune complexes at diagnosis in children with neuroblastoma, osteogenic sarcoma, ALL and AML.

To correlate serial levels of circulating immune complexes with disease activity should significant quantities be initially detected.

Technical Approach: Newly diagnosed and staged patients under 21 years of age with neuroblastoma, osteogenic sarcoma, acute lymphocytic leukemia or acute myelogenous leukemia are eligible. Patients should not have had excisional surgery, chemotherapy or radiotherapy prior to initial serum sample.

Progress: No patients have been registered on this protocol.

# Detail Summary Sheet

Date: 22 Nov 83 Proj No: POG 8104 Status: Ongoing

## TITLE:

Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III

Start Date 27 Jan 83 Est Comp Date: Unknown

Principal Investigator Facility

Terry E. Pick, M.D., LTC, MC Brooke Army Medical Center

Dept/Sec Associate Investigators:

Department of Pediatrics

Key Words:

Neuroblastoma

|                            |                            |                          |
|----------------------------|----------------------------|--------------------------|
| Accumulative MEDCASE Cost: | Est Accumulative OMA Cost: | Periodic Review Results: |
|----------------------------|----------------------------|--------------------------|

Objectives: To treat the tumor according to age and stage at which the tumor was diagnosed.

To reduce later complications by separating by age and stage those patients that require surgery only; surgery and chemotherapy; surgery, chemotherapy, and radiation therapy.

Technical Approach: Therapy will follow the schema outlined in the study protocol.

Progress: Four patients have been entered on this study. Three are alive and one has expired. It is too early to report any significant progress.

## AUTHOR INDEX

### A

Allen, R.C. 31, 35, 48, 71, 73, 103, 123  
Anderson, J.H. 36, 37, 39, 42, 46, 95, 134  
Ayala, E.F. 34, 41, 51

### B

Bach, D.E. 214  
Bailey, A.D. 127  
Bailey, S.R. 91, 107  
Bates, L.A. 208  
Baysinger, C. 189, 196  
Bell, E.A. 135  
Bessen, R.J. 205  
Bickell, W.H. 64, 67  
Bilodeau, L.P. 53  
Blanton, H. 61  
Bode, D. 163, 175, 181, 191  
Boyd, J. 40, 100, 101, 105, 115, 116, 117, 126, 128, 217-318  
Boyle, D.J. 63  
Bronstein, A. 212  
Brown, D.L. 97, 133  
Brown, L. 169  
Bryant, K.R. 194  
Bunker, S. 159, 161  
Burgin, W.W. 210  
Burgos, V.L. 63  
Burleson, D.G. 32, 33, 35, 40  
Bush, B. 61, 120  
Butler, M.L. 121

### C

Cable, H. 80  
Capen, C.V. 138, 142, 319-344  
Carpenter, J.L. 108, 112, 125  
Caskey, J.T. 196  
Castro-Reyes, W 156  
Celio, P.V. 119  
Chapa, I. 152  
Chapman, L. 200  
Cherry, R.N. 65, 197  
Cohen, D.J. 193  
Cooney, M.D. 173  
Cowan, J.D. 318  
Cox, W.R. 96  
Craig, C. 211  
Craig, W. 64, 89, 90, 97, 102, 133

## D

Damore, S. 86, 107, 133  
Davis, C.E. 93, 108  
DeBakey, M.E. 67  
Dice, W.H. 63, 65, 66, 67  
D'Silva, N. 75, 125  
Dudley, M. 150

## E

Ernst, G.P. 205  
Ernst, J.J. 180, 183, 190, 195  
Etzkorn, E.T. 118b

## F

Foreman, C.S. 143  
Foulks, C.J. 69, 77, 82, 84  
Friess, G. 116  
Fritz, A.L. 160

## G

Gallinger, K.D. 182  
Gangai, M.P. 165, 167, 171  
Garcia, M.D. 140  
Gardner, F.M. 216  
Geer, M.R. 64  
Georgitis, W.J. 94, 99, 130, 134  
Gierbolini, J.I. 215  
Glass, T.G. 70  
Glendening, D. 61  
Goldner, F. 127, 131  
Gordon, D.J. 63, 186  
Gray, M. 148  
Grasiadei, J.M. 203  
Gregory, W. 177  
Griffith, D. 163, 174  
Gunn, B.A. 50

## H

Haley, J.A. 131  
Hamelink, J.K. 172  
Harper, B.W. 213  
Hartshorne, M. 99, 160, 161  
Harvey, W.H. 79, 100, 128, 129, 160  
Hays, M.J. 201  
Herrick, C.N. 136, 140  
Hillis, R.E. 213  
House, A. 211  
Hume, R.F. 145

I

J

James, K.D. 198  
Jeffreys, C.A. 136  
Jirak, G. 144  
Johnson, K. 207  
Joyce, E. 128, 147, 151  
Juchau, S.V. 171, 174  
Judah, M.W. 214

K

Kane, M.D. 202  
Keeling, J. 87  
Kinsman, R.L. 65  
Knapp, W.G. 173  
Kotulak, J.C. 173  
Krakow, A.M. 212  
Kraus, E.W. 75, 87, 113  
Kraut, R. 52, 53, 54, 56, 58, 59, 61, 62  
Krikorian, D.J. 47, 151  
Kunkel, J.M. 168

L

Landry, A.J. 161  
Latham, R. 114  
Lewis, C.W. 75, 104  
Lieberman, M.M. 34, 41, 43, 44  
Lombardo, F. 129  
Longoria, R.R. 88, 106  
Lugo, E.J. 155

M

Manuel, L. 188  
Mark, J.E. 142  
Markey, K.L. 187, 188  
Matson, A.E. 206  
Matthews, J.I. 118a, 120, 124  
Matthews, R.J. 65  
Mattox, K. 67  
McAllister, C.K. 93, 98, 109, 110, 171  
McCollough, M. 87  
McCracken, J.D. 217-318  
Mead, M. 31  
Merrill, G.A. 31, 36, 37, 48  
Mills, G.M. 70, 71, 73, 74, 100, 101, 128, 307, 312, 345-347  
Murgo, J.P. 64, 76, 86, 90, 102, 114, 133  
Murray, T. 107



N

Nauschuetz, W.F. 50, 149  
Norris, T.J. 189

O

O'Hara, M.A. 191  
Orr, M.A. 209  
Ortiz, R. 184

P

Pagani, M. 89  
Parry, W.H. 153  
Pasipoulardis, A.D. 89  
Peake, J.B. 170, 178, 196  
Pedersen, C.E. 46  
Peek, M. 31  
Perkins, T.A. 158  
Perkner, J.J. 127, 131  
Pick, T.E. 71, 152, 185, 348-367  
Piwinski, S.E. 186  
Posch, J.J. 70, 101  
Pottenger, F.J. 200  
Pupa, L. 112, 121

Q

R

Ramirez, D.A. 68, 72, 82, 85, 95, 111, 132  
Ramirez, R. 162  
Rastrelli, A. 178  
Rathofer, S.A. 217  
Reeb, B. 70, 101  
Reed, B. 207  
Reside, G.J. 60  
Rice, M.M. 66  
Robertson, A.W. 138  
Rosen, J. 150  
Rosenthal, D. 176  
Rubal, B.J. 76, 86, 91, 96, 107

S

Salasche, S.J. 122  
Satterfield, M.J. 199  
Sauri, M.A. 125  
Schatz, R.A. 92  
Seymour, C.J. 207  
Sharr, M. 204  
Shaw, C. 127  
Shaw, T. 178

S (cont.)

Shumski, E.J. 125, 138, 190, 192, 195  
Sinegal, J.H. 35  
Spence, C.R. 165, 167, 171, 177, 180, 184, 190, 192, 195  
Spiva, D. 104  
Stapleton, L.M. 129  
Suchko, G.D. 57, 62  
Sullivan, C. 120, 124  
Sutton, A. 142

T

Taylor, T.J. 78, 94, 97, 105, 115, 117, 130, 134  
Telepak, R.J. 99  
Thompson, I.M. 167, 171, 177, 180, 184, 190, 192, 195  
Troxell, M. 105

U, V

Vaughn, G.K. 35  
Venters, W. 154  
Via, C.S. 103, 123

W

Wahlgren, V.E. 188  
Wallace, R.W. 136, 141, 143, 144, 145, 146  
Walters, M.J. 164, 166  
Webb, D.L. 185  
Wesen, C.A. 166  
Westerhoff, N. 76, 114  
Whitfield, J.A. 211  
Wilson, F.P. 160  
Wolcott, K. 40  
Wright, L.F. 80, 82, 84

X, Y, Z

Zumbrun, S. 92

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